MINISTÉRIO DA EDUCAÇÃO
UNIVERSIDADE FEDERAL DE GOIÁS
INSTITUTO DE PATOLOGIA TROPICAL E SAÚDE PÚBLICA

PAULO MOACIR DE OLIVEIRA CAMPOLI

VALIDAÇÃO DA GASTROSTOMIA ENDOSCÓPICA PERCUTÂNEA REALIZADA PELA TÉCNICA DE PUNÇÃO COM O USO DE UMA NOVA VARIANTE TÉCNICA DE GASTROPEXIA

Goiânia

2010

PAULO MOACIR DE OLIVEIRA CAMPOLI

VALIDAÇÃO DA GASTROSTOMIA ENDOSCÓPICA PERCUTÂNEA REALIZADA PELA TÉCNICA DE PUNÇÃO COM O USO DE UMA NOVA VARIANTE TÉCNICA DE GASTROPEXIA

Tese de Doutorado apresentada ao Programa de Pós-Graduação em Medicina Tropical e Saúde Pública do Instituto de Patologia Tropical e Saúde Pública da Universidade Federal de Goiás, como requisito parcial para obtenção do Título de Doutor em Medicina Tropical e Saúde Pública na Área de Concentração de Epidemiologia.

Orientadora: Prof[a]. Dr[a]. Marília Dalva Turchi

Goiânia

2010

Dados Internacionais de Catalogação na Publicação (CIP)
GPT/BC/UFG

C198v

Campoli, Paulo Moacir de Oliveira.
Validação da gastrostomia endoscópica percutânea realizada pela técnica de punção com o uso de uma nova variante técnica de gastropexia [manuscrito] / Paulo Moacir de Oliveira Campoli. - 2010.
111 f. : Il. figs, tabs.

Orientadora: Profª. Drª. Marília Dalva Turchi.
Tese (Doutorado) – Universidade Federal de Goiás, Instituto de Patologia Tropical e Saúde Pública, 2010.
Bibliografia.

1. Gastrostomia endoscópica percutânea. 2. Endoscopia digestiva. 3. Gastropexia. 4. Sitio cirúrgico – Infecção. I.Título.

CDU: 616.33:616-089.8

Programa de Pós-Graduação em Medicina Tropical e Saúde Pública da Universidade Federal de Goiás

BANCA EXAMINADORA DA TESE DE DOUTORADO

Aluno: Paulo Moacir de Oliveira Campoli

Orientadora: Profª. Drª. Marília Dalva Turchi

Membros:

1. **Profª. Drª. Marília Dalva Turchi**
2. **Prof. Dr. Ricardo de Souza Kuchenbecker**
3. **Prof. Dr. Kiyoshi Hashiba**
4. **Prof. Dr. Claudemiro Quireze Júnior**
5. **Profª. Drª. Cristiana Maria Toscano Soares**

Data: 16/12/2010

DEDICATÓRIA

À Márcia, minha amada companheira e aos nossos queridos filhos Clara e Heitor.

AGRADECIMENTOS

Aos meus pais, João Campoli e Ivanilce de Oliveira Campoli pelo grande esforço feito para proporcionar aos filhos uma esmerada educação,

À minha filha Clara Moraes Campoli, pela relevante contribuição com seus conhecimentos da língua inglesa,

Ao Programa de Pós-Graduação em Medicina Tropical e Saúde Pública do IPTSP, por disponibilizar uma bela estrutura de ensino fundamentada num corpo docente de especial qualidade,

À minha orientadora Prof[a]. Dr[a]. Marília Dalva Turchi pelos sólidos ensinamentos, pelas preciosas sugestões dadas em cada etapa deste estudo, pela forma paciente de lidar com cada nova idéia e pela confiança depositada ao longo destes três anos,

Aos professores do Departamento de Saúde Coletiva do Instituto de Patologia Tropical e Saúde Pública, Prof[a]. Dr[a]. Ana Lúcia Sampaio Sgambatti de Andrade, Prof[a]. Dr[a]. Celina Maria Turchi Martelli e Prof. Dr. João Bosco Siqueira Júnior que sempre apoiaram, incentivaram e acompanharam com especial interesse a realização deste estudo,

Aos membros da banca de avaliação do processo de progressão para doutorado, Prof. Dr. João Bosco Siqueira Júnior, Prof. Dr. Claudemiro Quireze Júnior e Prof. Dr. Joffre Rezende Filho pelas importantes contribuições dadas nesta etapa,

Aos membros da banca de qualificação, Profª. Drª. Celina Maria Turchi Martelli, Profª. Drª. Cristiana Maria Toscano Soares e Prof. Dr. Paulo Gonçalves de Oliveira, por terem disponibilizado tempo e conhecimentos que contribuíram sobremaneira para uma melhor estruturação deste estudo,

À Associação de Combate ao Câncer em Goiás e ao Hospital Araújo Jorge por proporcionarem condições de trabalho que permitem a execução de projetos desta envergadura,

Aos meus amigos e companheiros de trabalho do Setor de Aparelho Digestivo do Hospital Araújo Jorge - Goiânia, Dr. Orlando Milhomem da Mota, Dr. Osterno Queiroz da Silva, Dr. Jales Benevides Santana Filho, Dr. Paulo Adriano de Queiroz Barreto e Dr. Alexandre Menezes de Brito, por terem apoiado e estimulado a realização desta empreitada,

À minha amiga e companheira de trabalho do Setor de Endoscopia Digestiva do Hospital Araújo Jorge - Goiânia, Drª. Daniela Medeiros Milhomem Cardoso pelas relevantes contribuições, sem as quais este estudo não teria sido bem sucedido,

Ao grande amigo Dr. Flávio Hayato Ejima, companheiro de trabalho em endoscopia digestiva em Brasília-DF e em Goiânia-GO, pela forma desprendida de contribuir com seus conhecimentos, experiência e habilidade técnica,

Aos amigos do Setor de Cabeça e Pescoço do Hospital Araújo Jorge - Goiânia, Dr. Waldir de Castro Quinta, Drª. Maria Paula Curado, Dr. José Carlos de Oliveira, Dr. Márcio Roberto Barbosa da Silva, Dr. Antonio Paulo Machado Gontijo, Dr. Alexandre João Meneghini e Dr. Renato Moreira Aguiar pelo incondicional apoio ao projeto de realização de gastrostomia nos seus pacientes,

Às várias turmas de residentes em oncologia do Hospital Araújo Jorge - Goiânia por proporcionarem as condições para a aquisição de conhecimentos básicos de epidemiologia clínica através das nossas atividades semanais,

Ao grande amigo Dr. Adriano Augusto Peclat de Paula e à dileta amiga Dr[a]. Luana Gomes Alves que prestaram importante contribuição na etapa final deste estudo,

À Secretaria de Saúde do Distrito Federal, aos Diretores do Hospital Regional de Taguatinga-DF, às Chefias da Unidade de Cirurgia Geral deste hospital e aos colegas cirurgiões desta Unidade, pela confiança e apoio na forma de dispensa de ponto para execução deste projeto, sem a qual não teria sido possível realizar um trabalho com esta dimensão,

Ao Prof. Dr. Marco Tulio Antonio García-Zapata, Dr. Edgar Berquó Peleja e Prof. Dr. Joffre Rezende Filho que em diversas ocasiões se interessaram, incentivaram e torceram pelo bom andamento deste estudo o que funcionou como forte estímulo, especialmente nas ocasiões de maior dificuldade,

A cada paciente que direta ou indiretamente contribuiu para o sucesso desta empreitada.

SUMÁRIO

FIGURAS E TABELAS

ANEXOS

SIGLAS E ABREVIATURAS

GEP	Gastrostomia Endoscópica Percutânea
EUA	Estados Unidos da América
N/D	Informação não disponível
SUS	Sistema Único de Saúde
ACCG	Associação de Combate ao Câncer em Goiás

RESUMO

Havendo incapacidade prolongada ou permanente de deglutir, na presença de via digestiva funcionante, a gastrostomia endoscópica percutânea (GEP) representa a principal alternativa para assegurar aporte nutricional. A GEP pela Técnica de Tração é muito utilizada por ser segura e de fácil execução, porém está associada a elevados índices de infecção periostomal. A GEP realizada pela Técnica de Punção parece estar associada a baixo risco de infecção, contudo requer uma fixação da parede gástrica à parede abdominal (gastropexia) o que torna o procedimento de difícil execução.

O presente estudo tem por objetivo descrever e validar um procedimento de GEP pela Técnica de Punção, que envolve uma nova variante técnica de gastropexia, além de demonstrar seus benefícios em relação ao risco de infecção periostomal.

Foi realizado um estudo descritivo da segurança e exequibilidade de uma nova variante técnica de gastropexia com agulha longa e curva. Em seguida foi realizado um estudo com delineamento do tipo antes-e-depois comparando duas técnicas de gastropexia. Foi feito também um ensaio clínico randomizado comparando tubos de gastrostomia de materiais diferentes (látex *versus* silicone). Ao final, foi realizada uma metanálise avaliando os riscos de infecção no sítio cirúrgico entre as Técnicas de Punção e de Tração.

Os resultados dos quatro estudos realizados estão apresentados na formato de quatro artigos científicos. O primeiro estudo revelou que a nova técnica de gastropexia com agulha longa e curva é segura e exequível e o segundo estudo mostrou que esta nova técnica de gastropexia está associada a menor risco de infecção que a técnica de gastropexia usada anteriormente. No terceiro estudo foi observado que os tubos de silicone têm maior durabilidade que os tubos de látex e a metanálise demonstrou que a GEP pela Técnica de Puxar está associada a maior risco de infecção que a Técnica de Punção.

ABSTRACT

Percutaneous endoscopic gastrostomy (PEG) currently represents the main alternative to ensure nutritional supply in patients with prolonged or permanent inability to swallow, and yet has a functional gastrointestinal tract. PEG performed with the Pull Technique is widely used because it is easy to perform and very safe, although it is associated with high infection rates. The Introducer Technique appears to be associated with a lower infection risk, although it requires fixation of the gastric wall to the abdominal wall (gastropexy), which makes the procedure difficult to perform.

This study sought to describe and validate PEG performed with the Introducer Technique with the use of a new technical gastropexy variant, besides demonstrating its benefits in relation to risk of peristomal infection.

A descriptive study of the safety and feasibility of a new technical gastropexy variant with a long curved needle was performed. We then compared the two gastropexy techniques in a before-and-after design. A randomized clinical trial comparing gastrostomy tubes constructed of different materials (latex *vs.* silicone) was also conducted. Finally, we performed a meta-analysis evaluating peristomal infection risk between the Introducer Technique and Pull Technique.

The results of these four studies are presented in four separate papers. The first study showed that the new technical gastropexy variant that uses a long curved needle is safe and feasible. The second study showed that it is associated with a lower risk of infection compared with the gastropexy technique used previously. The third study found that the silicone tubes have greater durability than latex tubes. The final meta-analysis showed that PEG performed with the Pull Technique is associated with a greater risk of infection than the Introducer Technique.

1. INTRODUÇÃO

São diversas as doenças que causam perda transitória ou permanente da capacidade de deglutir. Nesta condição o aporte calórico deve ser obtido por via enteral ou por via parenteral. Havendo via digestiva acessível e funcionante, a preferência é pela alimentação enteral. Nesta circunstância, a sonda nasoenteral é muito utilizada, particularmente quando o seu uso está limitado a um período inferior a 30 dias. Para períodos maiores que este, a gastrostomia se impõe com o objetivo de evitar as complicações e o incômodo do uso prolongado da sonda nasoentérica (Wong & Ponsky 2000).

Classicamente, a gastrostomia é implantada por métodos cirúrgicos convencionais o que exige internação hospitalar, utilização de sala de cirurgia, concurso do anestesista, além de laparotomia ou laparoscopia para sua execução. Há cerca de 30 anos várias opções técnicas utilizando recursos da radiologia intervencionista (Sacks & Glotzer 1979, Preshaw 1981) ou da endoscopia digestiva (Gauderer et al. 1980, Hashiba 1980) foram descritas para a execução da gastrostomia. O advento desta nova modalidade técnica, denominada gastrostomia percutânea (seja radiológica ou endoscópica) tornou mais simples, mais seguro, associada a menor morbidade e passou a substituir o método cirúrgico convencional já consagrado (Ljungdahl & Sundbom 2006).

A Gastrostomia Endoscópica Percutânea (GEP) realizada pela Técnica de Tração (*Pull Technique*) e descrita por Gauderer *et al* (1980) constitui a maneira mais usual de realizar gastrostomia em todo o mundo (Gauderer 2002). Isto se deve à sua simplicidade, facilidade de execução, bons resultados e disponibilidade de material industrializado adequado à realização desta técnica. São desvantagens deste método os elevados índices de infecção local (Ahmad et al. 2003) e o risco de implante tumoral no sítio cirúrgico em pacientes com

neoplasia maligna (Cappell 2007). Além disso, esta técnica não proporciona uma adequada fixação do estômago à parede abdominal (gastropexia).

Existe um método alternativo para realização de GEP denominado Técnica de Punção (*Introducer Technique*) que comporta menor risco de infecção cirúrgica (Horiuchi et al. 2008), menor risco de implante tumoral (Cappell 2007) e um sistema de gastropexia seguro, pois geralmente é feito com fios de sutura. A desvantagem desta técnica está na sua maior dificuldade de execução, especialmente na etapa da gastropexia.

Na Associação de Combate ao Câncer em Goiás (ACCG) optamos por utilizar a Técnica de Punção e diante da dificuldade em realizar a gastropexia, desenvolvemos uma nova variante técnica de aplicação dos pontos de sutura com agulha longa e curva, que pretende tornar esta etapa de fácil execução, mantendo as demais vantagens do método.

A ACCG é uma instituição filantrópica responsável pelo atendimento de pacientes portadores de neoplasias malignas, procedentes do nosso estado e de vários estados vizinhos. A ACCG, fundada em 1956, é uma associação civil de caráter beneficente com personalidade jurídica de direito privado e a maioria dos seus pacientes é atendida pelo Sistema Único de Saúde (SUS). A ACCG mantém o Instituto de Ensino e Pesquisa, sendo a Residência Médica em Oncologia (Cirurgia Oncológica, Oncologia Clínica e Radioterapia) uma das suas principais atribuições.

O Hospital Araújo Jorge, localizado em Goiânia, é a unidade hospitalar da ACCG. Conta com 211 leitos de internação e no ano de 2009 foram cadastrados 16.124 novos pacientes. Na sua estrutura administrativa e organizacional, estão incluídos o Setor de Aparelho Digestivo e o Setor de Cabeça e Pescoço, que prestam atendimento à maior parte dos pacientes que irão necessitar de gastrostomia durante alguma etapa do seu tratamento.

A GEP realizada no HAJ tem algumas particularidades que serão objetos de estudo nesta Tese:

1. As gastrostomias são executadas pela Técnica de Punção e não pela Técnica de Tração,

2. A gastropexia passou a ser realizada através de dois pontos de sutura aplicados com agulha longa e curva,
3. O tubo de gastrostomia utilizado é a sonda de Foley fabricada com látex.

O processo de validação é uma etapa fundamental por ocasião da implantação de novas tecnologias em saúde, como por exemplo, esta forma de executar GEP. A validação de novas tecnologias na área cirúrgica constitui objeto de muitas discussões e controvérsias (Anyanwu & Treasure 2004, Piantadosi 2005, Kassell & Dumont 2006). O melhor método de validação é o uso de ensaios clínicos randomizados comparando os resultados da nova tecnologia com placebo ou com a tecnologia existente, no entanto, são muitas as dificuldades na implementação deste delineamento nos novos procedimentos cirúrgicos. A alternativa tem sido avaliar novas tecnologias na área cirúrgica com estudos observacionais (Ridgway & Darzi 2002, Cooper et al. 2008).

O processo de validação da GEP aqui estudada está fundamentado em quatro estudos que formam o corpo desta tese de doutoramento e que será apresentada no formato de artigos científicos. Uma nova variante técnica de gastropexia com uma agulha longa e curva foi descrita, acompanhada da avaliação da sua segurança e exequibilidade; numa etapa posterior foi elaborado um estudo comparando a nova variante técnica de gastropexia com agulha longa e curva com a técnica de gastropexia com duas agulhas retas utilizada anteriormente; a seguir foi conduzido um ensaio clínico randomizado comparando tubos de gastrostomia feitos de dois materiais diferentes (látex *versus* silicone) e por fim uma metanálise comparando o risco de infecção entre as duas técnicas de GEP (Técnica de Tração *versus* Técnica de Punção). O produto final compreende, portanto, quatro artigos referentes a cada um destes quatro estudos, o primeiro deles já publicado na revista *BMC Gastroenterology*, o segundo foi submetido à revista *Acta Gastroenterológica Latinoamericana*, o terceiro já aceito e publicado *online* na revista *Digestive Endoscopy* e o quarto foi submetido à apreciação da revista *Endoscopy*.

2. REVISÃO DA LITERATURA

2.1. HISTÓRICO

2.1.1. Gastrostomia Cirúrgica

Gastrostomia foi executada pela primeira vez por cirurgia convencional por meio de laparotomia por Sédillot (1849), contudo, complicações operatórias e óbito do paciente fizeram com que o procedimento não fosse utilizado rotineiramente. A primeira gastrostomia bem sucedida foi realizada em 1875 pelo cirurgião inglês Sydney Jones (1875). No ano seguinte Verneuil (1876) também realizou uma gastrostomia descrita como bem sucedida por ter sido feita a fixação da parede anterior do estômago à parede abdominal com um fio de prata. Desde então diversas variantes técnicas de fixação gástrica foram relatadas, sendo que a maneira proposta por Stamm (1894) é utilizada de forma rotineira pelos cirurgiões há mais de um século (Minard 2006).

2.1.2. Gastrostomia Radiológica Percutânea

O primeiro relato de gastrostomia sem laparotomia foi apresentado por Jascalevich (1967). Os procedimentos foram realizados em 25 cães mantidos sob anestesia venosa. Com uma cânula orogástrica foi obtida distensão do estômago por meio de insuflação de ar, forçada por esfigmomanômetro. A câmara gástrica distendida era localizada por palpação e percussão e em seguida uma punção percutânea com trocarte era feita e introduzida uma sonda de Foley no interior do estômago. A fixação da parede anterior do estômago à parede abdominal era obtida pelo próprio balonete da sonda de Foley. Naquela ocasião o autor sugeriu que o método era adequado aos pesquisadores que trabalhavam em laboratórios com animais de grande porte. Preconizou também que esta técnica poderia ter utilidade clínica em pacientes comatosos, com sequelas de acidentes vasculares encefálicos ou com traumatismos cranianos, seja para aspiração gástrica ou para alimentação.

Somente doze anos depois, o método descrito por Jascalevich foi empregado por Sacks e Glotzer (1979) em dois pacientes que haviam retirado

seus tubos de gastrostomia colocados previamente por laparotomia. Neste relato observamos duas diferenças importantes em relação ao relato anterior: a punção da câmara gástrica foi orientada por fluoroscopia e ao invés de usar um trocarte, foi feita dilatação progressiva orientada por fio guia conforme a técnica de Seldinger (1953). Foi descrita como fácil e segura, pois os dois pacientes tinham a parede anterior do estômago aderida à parede abdominal.

Em 1981, o canadense Preshaw (1981), também utilizando os recursos da radioscopia, relatou o uso deste método de forma bem sucedida em 11 pacientes. A diferença em relação à publicação anterior foi que estes pacientes tiveram seus tubos de gastrostomias implantados pela primeira vez e, portanto, não tinham a parede gástrica aderida à parede abdominal. Além disto, Preshaw utilizou um trocarte semelhante ao já descrito por Jascalevich.

Em 1983 três publicações simultâneas, porém independentes reproduziram esta proposta em que o estômago era insuflado através de uma sonda nasogástrica e em seguida a câmara gástrica era acessada por punção percutânea guiada por radioscopia. Duas destas publicações são relatos de caso realizados no Canadá (Ho 1983, Tao & Gillies 1983). A terceira publicação é procedente dos EUA e se refere a uma pequena série de sete pacientes (Wills & Oglesby 1983). Chama a atenção o fato de que todas estas gastrostomias percutâneas foram realizadas sem qualquer mecanismo de fixação do estômago à parede abdominal e apenas no último artigo é feita uma referência a uma paciente que apresentou peritonite por vazamento de secreção gástrica. Os autores desta série de casos expressam sua preocupação com a necessidade de ancorar a parede gástrica à parede abdominal para evitar esta grave complicação (Wills & Oglesby 1983).

Um sistema de fixação da parede gástrica, engenhoso e ao mesmo tempo simples, designado fixador em T (*T-fastener*) foi descrito em 1986 (Brown et al. 1986) (Figura 1). Apesar de gerar uma controvérsia inicial acerca da necessidade do seu uso (Wills & Oglesby 1986), foi incorporado por muitos radiologistas (Ryan et al. 1997, Dewald et al. 1999, Lorentzen et al. 2007). Um estudo randomizado concluiu que a não utilização do fixador em T está

associada à ocorrência de complicações técnicas sérias e deve, portanto ser utilizado rotineiramente (Thornton et al. 2002).

Até os dias atuais a gastrostomia radiológica percutânea tem sido executada por profissionais afeitos aos procedimentos de radiologia intervencionista. A gastropexia é bastante realizada com uso do fixador em T e a introdução do tubo de gastrostomia tem sido executada pela técnica de Seldinger ou com uso de um trocarte especialmente desenhado para esta finalidade (Laasch & Martin 2007).

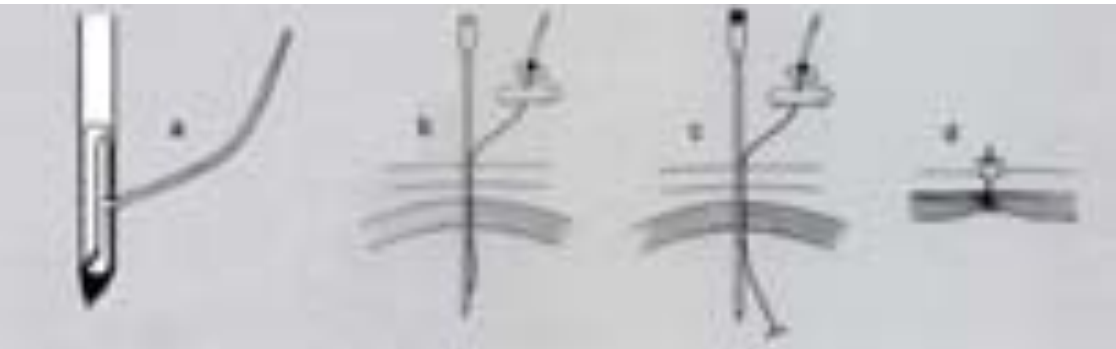


Figura 1. Gastropexia com o fixador em T
1a: Fixador em T dentro da agulha especialmente recortada para recebê-lo.
1b: A agulha com o fixador em T introduzada na cavidade gástrica por punção percutânea.
1c: Introdução do mandril da agulha para liberar a haste do fixador em T.
1d: Após a retirada da agulha a haste mantem fixa a parede gástrica.
Brown AS. *et al.* - Radiology 1988; 158:543-5
(modificado e reproduzido com permissão do autor)

2.1.3. Gastrostomia Endoscópica Percutânea

No ano de 1980 dois centros independentes descreveram a gastrostomia percutânea não cirúrgica com os recursos disponibilizados pela endoscopia digestiva, desde então denominada Gastrostomia Endoscópica Percutânea (GEP).

A primeira publicação foi realizada pelo professor Kiyoshi Hashiba (1980) à época cirurgião e endoscopista da Faculdade de Medicina da Universidade de São Paulo, que relatou em janeiro de 1980 a execução de gastrostomia, inicialmente em 13 cães e em seguida em dez pacientes. A técnica utilizada envolvia a aplicação de vários pontos de suturas transfixantes em U, envolvendo

a parede abdominal e a parede anterior do estômago (Figuras 2a e 2b). Em seguida era efetuada uma punção percutânea da cavidade gástrica com um trocarte e um tubo de gastrostomia do tipo Levine era introduzido (Figura 2c).

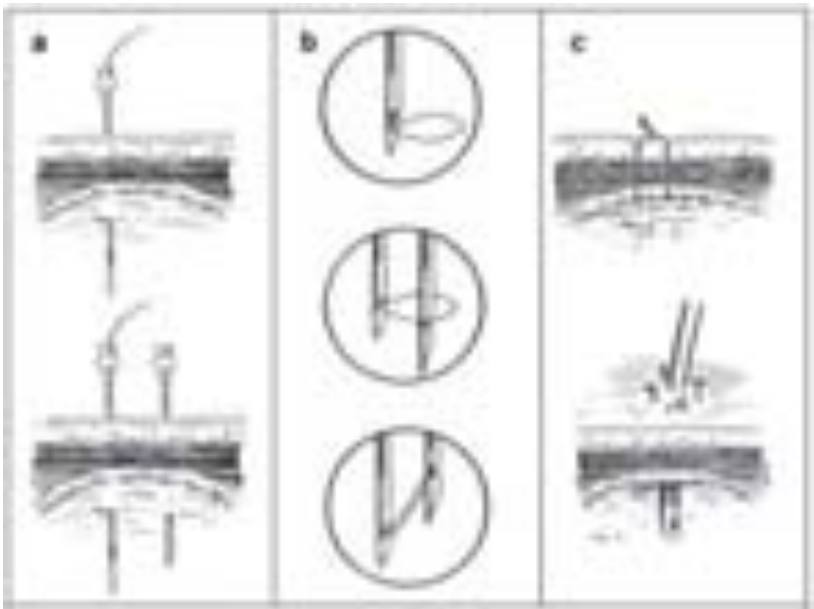


Figura 2. Gastropexia com duas agulhas retas.
2a: Duas punções com duas agulhas retas, uma delas com com um fio em laço e a outra agulha com uma ranhura.
2b: O laço é aprendido pela ranhura e ao retirar as duas agulhas é obtido um ponto em U.
2c: Vários pontos fixam o estômago à parede abdominal e um tubo é inserido por punção percutânea.

Hashiba K. - *Rev Paul Med* 1980;96:37-8
(modificado e reproduzido com permissão do autor)

O segundo relato de GEP foi apresentado pelos autores Michael Gauderer, Jeffrey Ponsky e Robert Izant Jr de Cleveland, Ohio, por ocasião do 11º. Congresso Anual da Associação Americana de Cirurgia Pediátrica que aconteceu em maio de 1980 na Flórida – EUA. Em dezembro de 1980 esta experiência inicial foi publicada no *Journal of Pediatric Surgery* (Gauderer et al. 1980). O método proposto por estes autores era a punção percutânea da cavidade gástrica com agulha, de forma que um fio longo, introduzido por esta agulha, se

apresentava no interior do estômago. Este fio era apreendido pelo endoscopista com uma alça de polipectomia e tracionado no sentido retrógrado até se exteriorizar pela boca (Figuras 3a, 3b e 3c). Em seguida, um tubo de gastrostomia era preso à extremidade oral deste fio longo o que proporcionava a possibilidade de tração do tubo de gastrostomia em sentido anterógrado até sua exteriorização pela parede abdominal. A parede anterior do estômago é mantida em aposição à parede abdominal por uma dilatação cilíndrica da extremidade gástrica do tubo, em forma de cogumelo e que funciona como um anteparo interno (Figuras 3d e 3e). Nesta publicação inicial, este procedimento foi executado em 12 crianças e em 19 adultos, de forma bem sucedida.

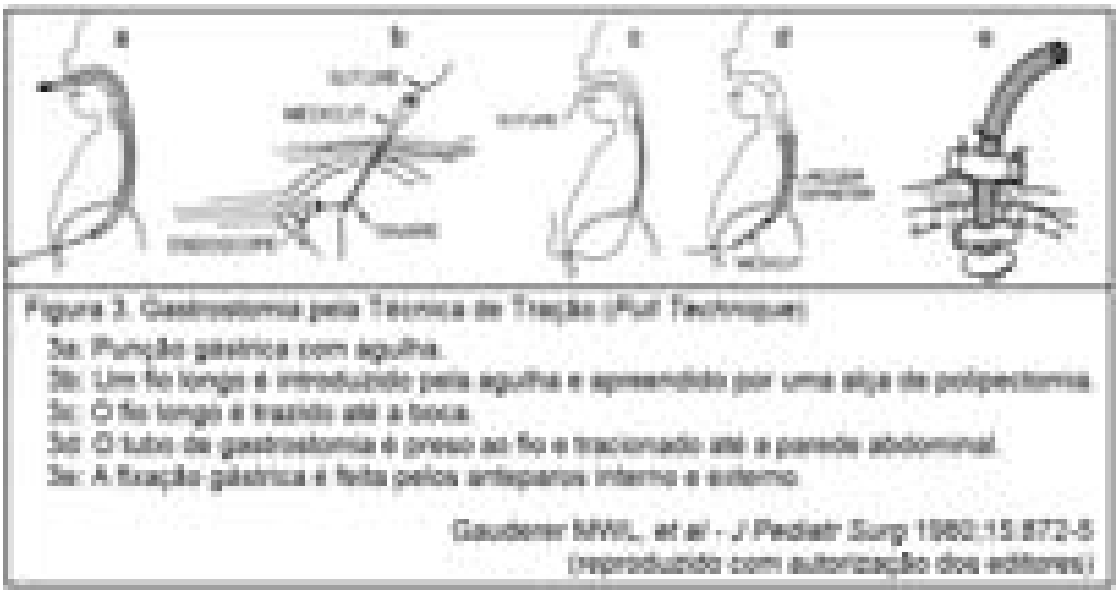


Figura 3. Gastrostomia pela Técnica de Tração (Pull Technique)
3a: Punção gástrica com agulha.
3b: Um fio longo é introduzido pela agulha e apreendido por uma alça de polipectomia.
3c: O fio longo é trazido até a boca.
3d: O tubo de gastrostomia é preso ao fio e tracionado até a parede abdominal.
3e: A fixação gástrica é feita pelos anteparos interno e externo.
Gauderer MWL, et al - J Pediatr Surg 1980;15:872-5
(reproduzido com autorização dos editores)

Este método proposto por Gauderer *et al*, denominada Técnica de Tração substituiu com grande vantagem a gastrostomia feita por laparotomia. Por ser simples, segura e de fácil execução, a técnica proposta por estes autores se mostrou reprodutível e rapidamente ganhou aprovação dos endoscopistas. Desde que foi descrita, é a maneira mais utilizada para se realizar GEP e seu uso tem se disseminado por todo o mundo (Gauderer 2002). Ao longo destas três décadas, a indústria de material médico tem se esmerado em produzir tubos de

gastrostomia especialmente desenhados para proporcionar uma execução confortável e segura desta técnica.

2.1.4. GEP pela Técnica de Punção

A técnica proposta por Hashiba é denominada Técnica de Punção, pois se utiliza de uma punção percutânea com trocarte. Várias modificações na sua forma de execução foram descritas ao longo dos anos. A fixação da parede gástrica à parede abdominal (gastropexia) é a fase mais trabalhosa do método, é responsável pela sua baixa reprodutibilidade e é a etapa que recebeu diversas propostas de mudanças.

A primeira modificação deste item foi no sentido da não realização da gastropexia (como já acontecera com o método radiológico) e pertence a Russel *et al* (1984) que descreveram em 1984 uma elegante forma de realizar gastrostomia endoscópica pela Técnica de Punção. Estes autores reproduziram a técnica proposta pelos radiologistas citados anteriormente, com a diferença de que o trocarte era revestido por uma bainha cilíndrica feita de material fragmentável. Após a punção percutânea da parede anterior do estômago, o trocarte era retirado e a bainha cilíndrica permanecia no trajeto obtido, de forma a proporcionar a fácil introdução de uma sonda balonada de Foley 14 Fr. Após o balão da sonda de Foley ter sido insuflado, a bainha cilíndrica era removida. Por fim a parede anterior do estômago era mantida em aposição à parede abdominal por uma pequena tração exercida pelo balão da sonda de Foley. Este procedimento foi executado em 28 pacientes, tendo ocorrido apenas três complicações, sendo uma delas a retirada da sonda de Foley que exigiu abordagem cirúrgica para realização de nova gastrostomia.

Ainda que diversas outras publicações tenham reproduzido a técnica proposta por Russel *et al*, sem realizar gastropexia (Kozarek et al. 1986, Miller et al. 1986, Deitel et al. 1988, Miller et al. 1989, Kadota et al. 1991, Saunders et al. 1991, Crombleholme & Jacir 1993, Petersen & Kruse 1997, Maetani et al. 2003, Sabnis et al. 2006), no início dos anos 90 surgem os primeiros relatos do uso dos fixadores em T (Figura 1) para assegurar a aposição da parede gástrica à

parede abdominal (Akkersdijk et al. 1995, Morioka et al. 1995, Tucker et al. 2003, Foster et al. 2007), durante a realização de GEP. Curiosamente, Robertson *et al* (1996) usaram cateteres de embolectomia vascular de Fogarty para obter este efeito de gastropexia.

Conforme já citado, Hashiba (1980) publicou o uso de fios de sutura para fixar o estômago em 1980 e voltou a apresentar casuísticas maiores nos anos de 1984 (Hashiba et al. 1984) e 1987 (Hashiba 1987). Kiser *et al* (1999) também apresentaram uma maneira mais simples de realizar a gastropexia com fio de sutura em 1999. Tem havido uma crescente preocupação com a realização de gastropexia e alguns autores passaram a utilizar um dispositivo mecânico que proporciona a fácil aplicação de fios de sutura às paredes abdominal e gástrica (Figura 4). No ano 2000 e em 2006 Dormann *et al* apresentaram o uso deste equipamento com bons resultados (Dormann et al. 2000a, Dormann et al. 2006). Nos anos seguintes, diversos outros autores também apresentaram suas experiências com este tipo de aparelho (Saito et al. 2007, Toyama et al. 2007, Horiuchi et al. 2008, Shastri et al. 2008).

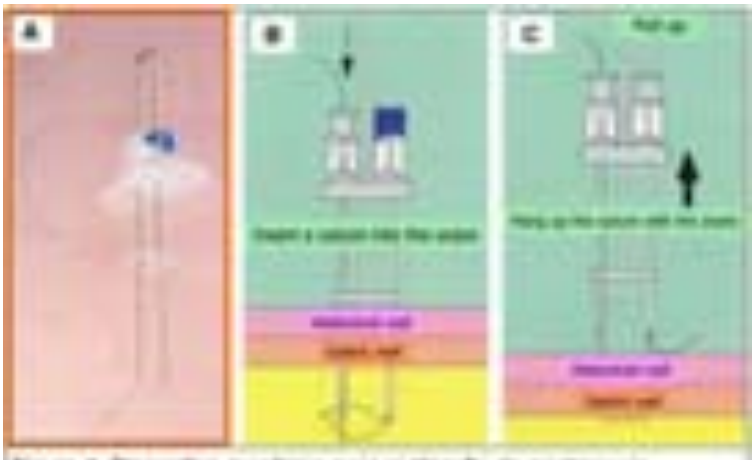


Figura 4. Dispositivo mecânico para realização de gastropexia
4a: Equipamento para gastropexia com duas agulhas retas de 20G, uma delas contendo uma alça e a outra contendo um fio de sutura monofilamentar 3-0.
4b: Após a punção gástrica, o fio é preso pela alça sob visão endoscópica.
4c: Ao remover todo o conjunto, um ponto em U é obtido.

Toyama Y, et al. - Surg Endosc 2007;21:2034-8
(reproduzido com autorização dos editores)

2.2. COMPLICAÇÕES DA GEP

A GEP é considerada um procedimento seguro, pois está associada a baixos índices de morbidade. Contudo, diversas complicações estão descritas, algumas delas com elevado potencial de gravidade e que merecem, portanto, especial atenção (Schrag et al. 2007). Discorreremos acerca das principais, levando em consideração a gravidade e a frequência com que ocorrem.

2.2.1. Vazamento periostomal

O vazamento ao redor do tubo de gastrostomia pode se constituir em complicação menor, quando a secreção gástrica se exterioriza pela pele. Esta condição pode ocorrer em até 12,3% dos pacientes submetidos à GEP, porém se reveste de pequena gravidade (Figueiredo et al. 2007).

Eventualmente o vazamento ocorre para a cavidade peritoneal o que se traduz em grave complicação e exige laparotomia para sua correção. Schurink *et al* (2001), avaliando 263 GEP, relataram 12 casos (4,6%) de vazamento ao redor do tubo de gastrostomia, sendo quatro deles com peritonite. Outro estudo também relatou 13 casos (9,6%) de vazamento intraperitoneal em 135 pacientes submetidos à GEP, com seis óbitos (4,4%) relacionados a esta complicação (Petersen & Kruse 1997). Nestes dois últimos estudos citados, foram utilizadas técnicas diferentes (Técnica de Tração no primeiro e Técnica de Punção no segundo), porém ambos têm em comum o fato de não ter sido realizada gastropexia. Existem controvérsias acerca do papel da gastropexia na prevenção desta complicação. Thornton *et al* (2002) publicaram um estudo randomizado comparando gastrostomias com ou sem gastropexia e não encontraram diferenças em termos de vazamento ao redor do tubo de gastrostomia. Em contrapartida, Tucker *et al* (2003) atribuíram à falta de gastropexia o fato de ter ocorrido quatro casos (8%) de vazamento entre pacientes submetidos à gastrostomia sem gastropexia, comparado a nenhum caso de vazamento entre os pacientes em que a gastropexia foi executada.

2.2.2. Lesão de vísceras abdominais

Ao realizar uma gastrostomia com o estômago pouco insuflado (Schrag et al. 2007) ou diante da presença de aderências por cirurgias prévias (Yamazaki et al. 1999), há risco de haver interposição de vísceras abdominais entre a parede gástrica e a parede abdominal o que pode gerar lesão iatrogênica. O cólon é o órgão mais exposto a este risco (Friedmann et al. 2007) embora haja descrições de lesões de outros órgãos como fígado (Fyock & Kethu 2009), baço e intestino delgado, estes menos frequentemente acometidos.

2.2.3. Síndrome do sepultamento do anteparo interno

Na literatura de língua inglesa é designada *buried bumper syndrome* e consiste na migração do anteparo interno do tubo de gastrostomia para o interior da parede gástrica ou mesmo da parede abdominal. Esta migração pode ser parcial, quando o alimento administrado ainda atinge a cavidade gástrica, ou pode ser total, sendo manifesta como se o tubo estivesse obstruído, além de haver sintomas dolorosos e/ou infecciosos no sítio cirúrgico. É complicação tida como pouco frequente, pois sua ocorrência é inferior a 3% conforme alguns autores (Horbach et al. 2007, Usuba et al. 2007) contudo, pode atingir índices superiores a 6% de acordo com outros relatos (Ma et al. 1995, Meine et al. 2007, Lee & Lin 2008). É interessante observar que praticamente não existe referência a esta complicação quando são utilizados tubos balonados (Schapiro & Edmundowicz 1996, Anagnostopoulos et al. 2003), sendo que, na literatura, há apenas um relato com este tipo de tubo de gastrostomia (Kim et al. 2006).

2.2.4. Infecção de sítio cirúrgico

A Técnica de Tração proposta por Gauderer *et al*, é de fácil execução e seu uso é disseminado mundialmente. Tem, contudo, a grande desvantagem de estar associada a altos índices de infecção local. Isto decorre do fato de ser um procedimento cirúrgico potencialmente contaminado, já que a introdução do tubo de gastrostomia se faz pela boca e pelo esôfago. Em decorrência da contaminação bacteriana, esta técnica está associada a índices de infecção

superiores a 20% (Jain et al. 1987, Akkersdijk et al. 1995, Preclik et al. 1999, Dormann et al. 2000b). Recentemente foram publicadas duas metanálises que compilaram estudos randomizados conduzidos para avaliar o efeito da profilaxia antimicrobiana nos índices de infecção de ferida em GEP feitas pela Técnica de Tração. Ambas demonstraram que o uso de antibiótico profilático reduz os índices de infecção para cerca de 8% (Lipp & Lusardi 2006, Jafri et al. 2007). Assim sendo, o uso de antibióticos é recomendado por ocasião da realização de GEP pela Técnica de Tração.

Tanto na gastrostomia radiológica quanto na GEP pela Técnica de Punção não há contaminação do tubo de gastrostomia pela microbiota da boca, pois ambas as técnicas são totalmente executadas por punção percutânea, com todos os rigores de assepsia e anti-sepsia. Na tabela 1 são apresentados os índices de infecção em séries já publicadas, cujos valores oscilam entre 0 e 3,6%. Dentre os estudos listados nesta tabela, observamos que alguns autores não fazem uso de profilaxia antimicrobiana (Saunders et al. 1991, Foster et al. 2007, Shastri et al. 2008).

Tabela 1. Infecção de sítio cirúrgico associada à GEP pela Técnica de Punção

Autor [ref]	Ano	Uso de antibióticos	Pacientes (n)	Infecção (n)	Infecção (%)
Russell *et al.*	1984	N/D	28	1	3,6
Hashiba	1987	N/D	56	0	0,0
Deitel *et al.*	1988	Sim	28	0	0,0
Miller *et al.*	1989	Sim	330	0	0,0
Kadota *et al.*	1991	N/D	89	3	3,4
Saunders *et al.*	1991	Não	136	1	0,7
Robertson *et al.*	1996	Sim	20	0	0,0
Maetani *et al.*	2003	Sim	29	0	0,0
Tucker *et al.*	2003	Sim	29	0	0,0
Dormann *et al.*	2006	Sim	46	1	2,2
Foster *et al.*	2007	Não	149	5	3,4
Saito *et al.*	2007	N/D	462	0	0,0
Toyama *et al.*	2007	Sim	30	1	3,3
Shastri *et al.*	2008	Sim	47	1	2,1
Shastri *et al.*	2008	Não	46	1	2,2
Horiuchi *et al.*	2008	Sim	68	0	0,0

N/D, informação não disponível

Só existe um estudo randomizado para avaliar a necessidade do uso de antibiótico nas gastrostomias realizadas por esta técnica (Shastri et al. 2008). Apesar de ter concluído que não há diferença nos índices de infecção entre o grupo que recebeu antibiótico e o grupo controle, trata-se de estudo com pequeno número de eventos e o seu poder (*power*) para descartar erro tipo II foi muito baixo (3%).

2.2.5. Implante de neoplasia no sítio cirúrgico

A Técnica de Tração proposta por Gauderer *et al* (1980), quando realizada em pacientes com neoplasia maligna em atividade (de cabeça e pescoço ou do esôfago), comporta um risco de causar implante tumoral no sítio cirúrgico, por contaminação direta, decorrente da passagem do tubo de gastrostomia pela neoplasia. Vários relatos de casos descrevem esta grave complicação. Cappell (2007) efetuou uma busca em diversas bases de dados disponíveis e apresentou uma revisão acerca deste assunto. Encontrou 44 casos de implante tumoral no sítio cirúrgico. Em todos, a localização do tumor primário era na faringe ou no esôfago e surgiram após três meses da execução da GEP. Em nenhum destes casos fora empregada a Técnica de Punção. Mesmo considerando que possa haver um viés de mensuração nesta análise, pois a quantidade de gastrostomias realizadas pela Técnica de Punção é muito menor que o número de gastrostomias realizadas pela Técnica de Tração, é razoável supor que a Técnica de Punção esteja associada a menor risco de implante tumoral, por não haver contato do tubo de gastrostomia com o tumor, durante a sua execução. Cruz *et al* (2005) avaliaram uma coorte de 218 portadores de câncer de faringe em atividade submetidos à GEP pela Técnica de Tração e encontraram dois casos de implante tumoral no sítio cirúrgico, o que fornece uma estimativa de incidência de 0,92%.

3. JUSTIFICATIVA

A GEP pela Técnica de Tração é amplamente utilizada em todo o mundo, assim como no Brasil, entretanto alguns estudos evidenciam elevados índices de infecção do sítio cirúrgico (Dormann et al. 2000b, Horiuchi et al. 2008) e também de implante tumoral com esta técnica (Cappell 2007).

Apesar de estar associada a baixos índices de infecção e de implante tumoral, a Técnica de Punção é pouco utilizada. É possível que esta baixa utilização se deva ao fato de haver maior dificuldade técnica na sua execução, especialmente na etapa da gastropexia.

Este estudo se justifica pela necessidade de validar a GEP pela Técnica de Punção associada a uma nova variante técnica de gastropexia utilizando uma agulha longa e curva, além da utilização de sonda de Foley fabricada com látex. Por ser uma variante técnica simples e de fácil execução, pretende-se prestar uma contribuição para tornar a realização da Técnica de Punção tão fácil e segura quanto a Técnica de Tração, aumentando assim a sua reprodutibilidade nos centros que se propõem a realizar GEP. Além disso, deverão ser mantidas ou melhoradas as vantagens desta técnica de GEP que são: baixo risco de infecção cirúrgica, baixo risco de implante tumoral, segurança e baixo custo.

4. OBJETIVOS

4.1. OBJETIVO GERAL

Descrever e validar um procedimento de GEP pela Técnica de Punção que envolve uma nova variante técnica de gastropexia e o uso de tubos de látex, além de demonstrar seus benefícios em relação aos índices de infecção de sítio cirúrgico.

4.2. OBJETIVOS ESPECÍFICOS

a. Descrever uma nova variante técnica de gastropexia com agulha longa e curva e demonstrar sua exequibilidade e segurança.

b. Comparar a nova variante técnica de gastropexia (agulha longa e curva) com a técnica de gastropexia utilizada anteriormente (duas agulhas retas) em relação às complicações infecciosas.

c. Comparar tubos de látex com tubos de silicone em relação à durabilidade, infecção, formação de tecido de granulação e vazamento.

d. Comparar a GEP feita pela Técnica de Punção com a GEP feita pela Técnica de Tração, em relação à infecção de sítio cirúrgico, através de Revisão Sistemática da literatura e Metanálise.

5. MÉTODOS

5.1. UNIDADE HOSPITALAR E POPULAÇÃO DE ESTUDO

No ano de 2009 o Hospital Araújo Jorge prestou atendimento a 337.242 pacientes, dos quais, 73% foram oriundos do sistema SUS. Neste ano, o Setor de Aparelho Digestivo e o Setor de Cabeça e Pescoço atenderam respectivamente 7.590 e 10.930 pacientes. Estes dois Setores atendem a uma grande demanda de portadores de câncer de esôfago ou de cabeça e pescoço que necessitam de gastrostomia durante seu tratamento. Até janeiro de 2003 as gastrostomias foram executadas por cirurgia convencional e a partir deste ano, passaram a ser realizadas majoritariamente por acesso endoscópico no Setor de Endoscopia Digestiva.

O Setor de Endoscopia Digestiva do Hospital Araújo Jorge conta com dois médicos especialistas, Dr. Paulo Moacir O. Campoli e Dra. Daniela Medeiros M. Cardoso, que participam da execução da totalidade das gastrostomias endoscópicas do Hospital. O Setor também conta com um médico especialista visitante, Dr. Flávio Hayato Ejima, que participou das fases iniciais de implantação das Técnicas de GEP utilizadas no Hospital Araújo Jorge. No ano de 2009 foram realizados 1.771 exames no Setor de Endoscopia Digestiva, incluindo 110 gastrostomias.

5.2. TÉCNICAS DE GEP

A GEP pela Técnica de Tração não é utilizada na nossa Instituição por três motivos:

1. O sistema SUS não provê ressarcimento do custo do material necessário para realização desta técnica,

2. A totalidade dos pacientes é constituída de portadores de neoplasia maligna e, portanto há o permanente risco de ocorrer implante tumoral no sítio cirúrgico com esta técnica, o que deve ser evitado em decorrência da gravidade desta complicação,

3. O elevado índice de infecção cirúrgica com esta técnica constitui restrição ao uso do método, especialmente em pacientes portadores de neoplasias de cabeça e pescoço ou de esôfago, pela sua condição de desnutrição e imunodepressão.

5.2.1. TÉCNICA DE PUNÇÃO E GASTROPEXIA COM DUAS AGULHAS RETAS

A partir de fevereiro de 2003 as gastrostomias que até então eram executadas por laparotomia, passaram a ser realizadas por via endoscópica através da Técnica de Punção. No período de fevereiro de 2003 a julho de 2004, a gastropexia foi realizada por sutura transfixante conforme proposto por Hashiba (1980), porém usando uma variação técnica descrita por Kiser *et al* (1999) que utilizavam duas agulhas retas (Figura 5). O trajeto pela parede abdominal era obtido por secção com bisturi e dissecção com tesoura (Figura 6) e a introdução do tubo de gastrostomia era realizada por punção com trocarte (Figura 7) conforme proposto por Jascalevich (1967) e já reproduzido por diversos outros autores (Kadota et al. 1991, Morioka et al. 1995, Gomez et al. 2000).

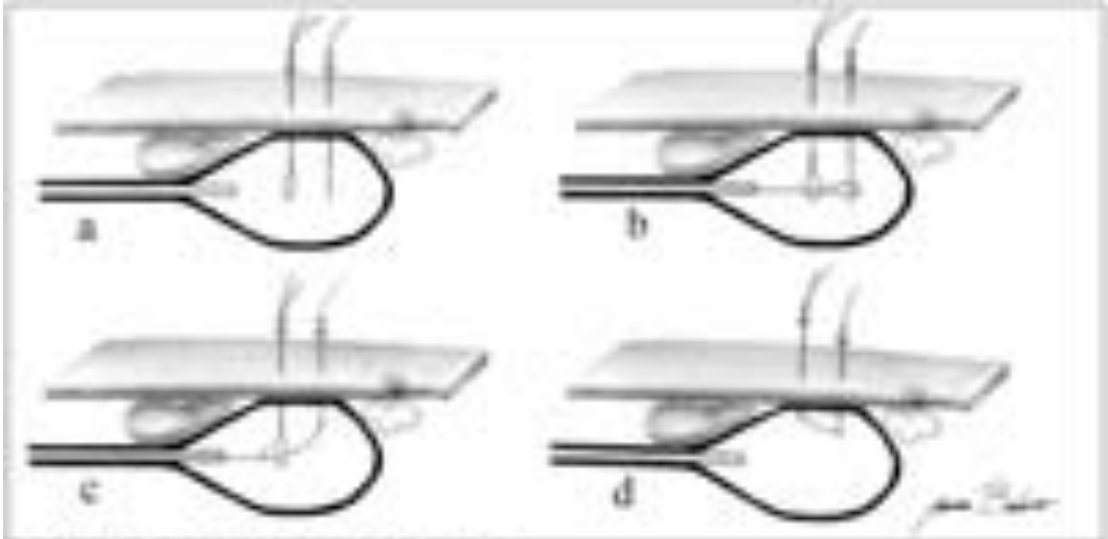


Figura 5: Gastropexia com duas agulhas retas

5a: Punção gástrica com as duas agulhas retas, uma contendo um fio solto e a outra contendo um laço.
5b: A alça de polipectomia passa por dentro do laço e apreende o fio solto.
5c: O fio solto é tracionado para o interior do laço pela alça de polipectomia.
5d: O laço apreende o fio solto e o tracione de volta à pele de forma a concluir o ponto em U.

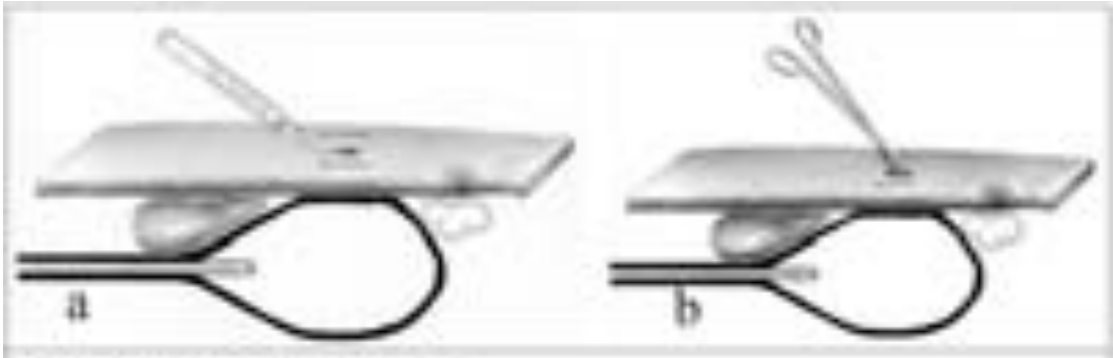


Figura 6: Trajeto pela parede abdominal

6a: Incisão da pele com bisturi.
6b: Dissecção com tesoura até a parede gástrica, sem perfurá-la.

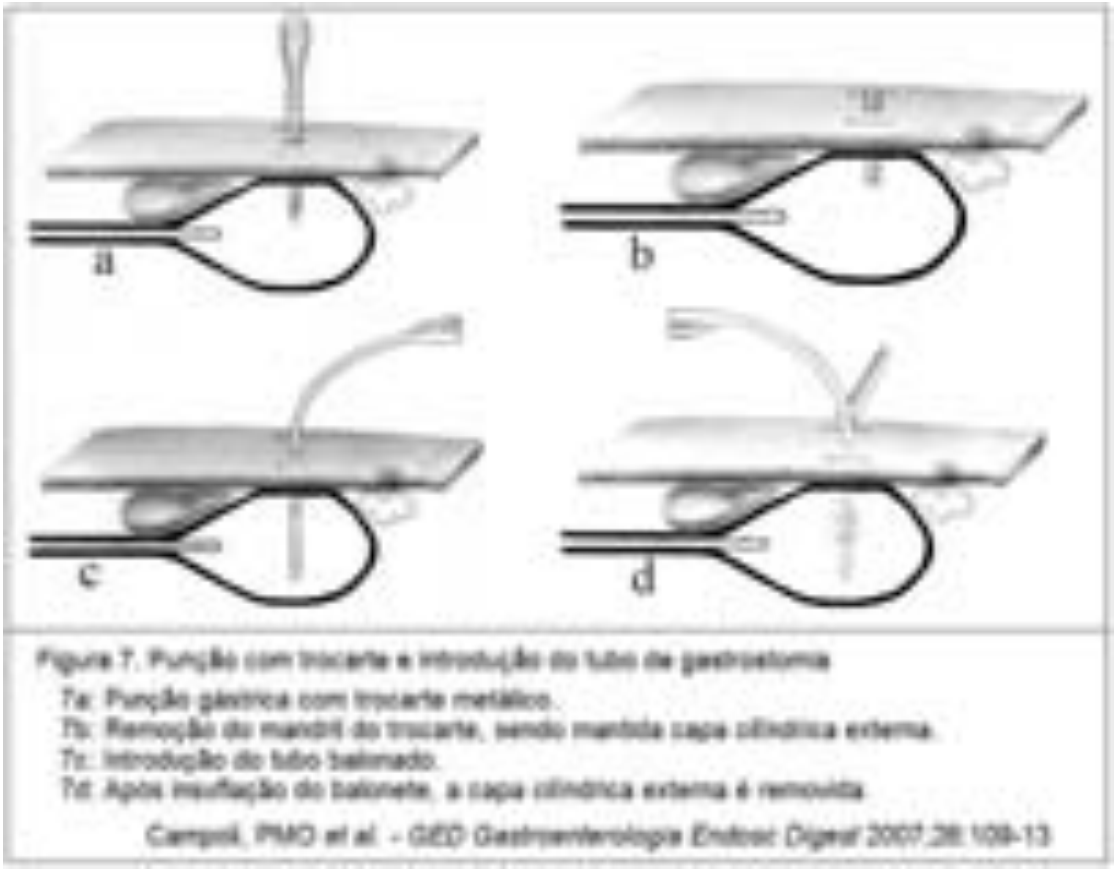


Figura 7. Punção com trocarte e introdução do tubo de gastrostomia
7a: Punção gástrica com trocarte metálico.
7b: Remoção do mandril do trocarte, sendo mantida capa cilíndrica externa.
7c: Introdução do tubo balonado.
7d: Após insuflação do balonete, a capa cilíndrica externa é removida.
Campoli, PMO et al. - GED Gastroenterologia Endosc Digest 2007;26:109-13

Neste período foram executadas 142 GEPs utilizando esta Técnica de Punção. Foram usados tubos de Foley feitos de látex e revestidos por uma fina camada de silicone. Não foi realizada profilaxia antimicrobiana. Morbidade operatória ocorreu em 13 casos (9,1%) dentre as quais quatro (2,8%) na forma de infecção do sítio cirúrgico (Campoli et al. 2007a). Em quase metade dos casos (46,5%), a GEP foi executada em pacientes com tumores irressecáveis de cabeça e pescoço (Campoli et al. 2007b).

A gastropexia com duas agulhas retas (Figura 5) utilizada neste período, traz consigo dois problemas. O primeiro é a dificuldade técnica em realizá-la. O segundo, mais grave, é que há contato da alça de polipectomia contaminada com o fio de sutura estéril e este fator pode estar associado a maiores índices de infecção do sítio cirúrgico. Com o propósito de solucionar estes dois problemas, foi idealizado um novo método de gastropexia com agulha longa e curva, cujo método está descrito a seguir.

5.2.2. TÉCNICA DE PUNÇÃO E GASTROPEXIA COM AGULHA CURVA

A partir de junho de 2004 a gastropexia passou a ser executada com uma agulha de 7,6 cm de comprimento e 1/2 círculo de curvatura, montada em fio de polipropileno 2 (Figura 8). O trajeto pela parede abdominal (Figura 6) e a introdução do tubo de gastrostomia (Figura 7) permaneceram sendo realizados da forma já relatada no tópico anterior.

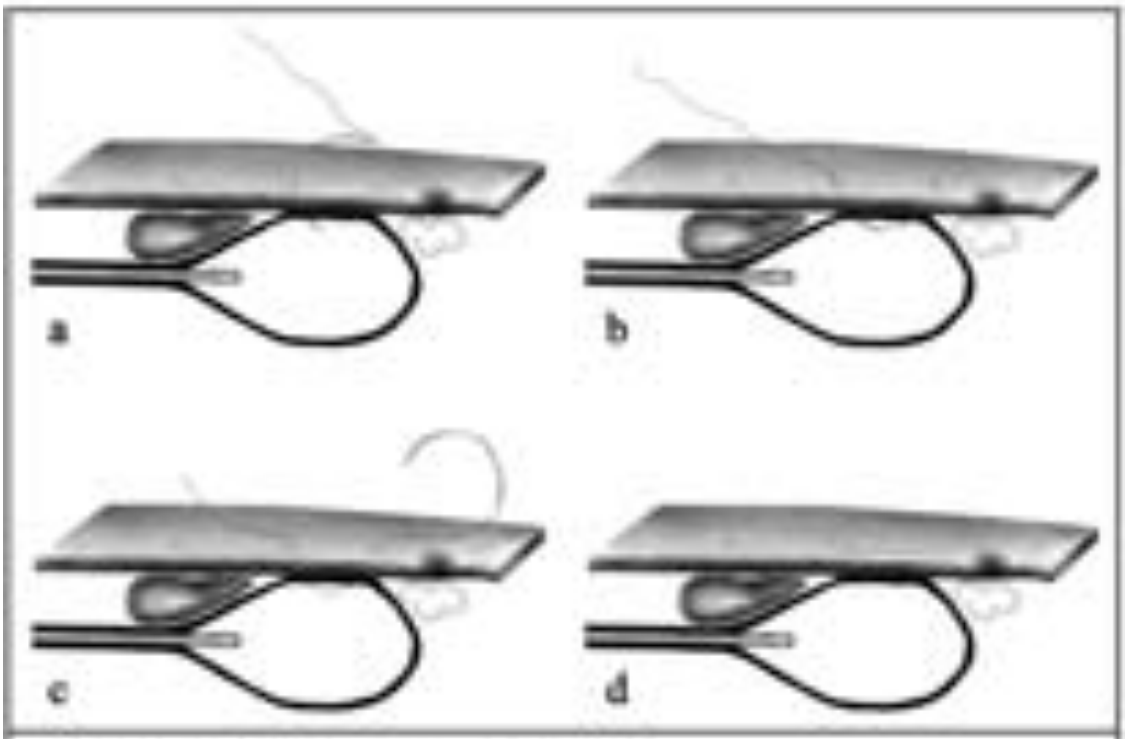


Figura 8. Gastropexia com uma agulha longa e curva
Sutura transfixante envolvendo as paredes abdominal e gástrica, realizada sob visão endoscópica (1a, 1b e 1c).
Um segundo ponto de sutura em "U" é aplicado, paralelo ao primeiro ponto (1d).

5.3. DELINEAMENTOS

Foram realizados quatro estudos cujos delineamentos estão discriminados abaixo:

a. Estudo descritivo e analítico da segurança e exequibilidade de uma nova variante técnica de gastropexia com agulha longa e curva.

b. Estudo com delineamento do tipo antes-e-depois (*before-and-after design*), comparando duas técnicas de gastropexia (duas agulhas retas *versus* uma agulha longa e curva).

c. Ensaio clínico randomizado comparando tubos de gastrostomia feitos de materiais diferentes (látex *versus* silicone).

d. Revisão sistemática e metanálise de estudos comparativos e de estudos observacionais comparando os riscos de infecção periostomal entre as Técnicas de Punção e de Tração.

6. RESULTADOS

Os resultados estão apresentados no formato de quatro artigos científicos conforme abaixo relacionados:

Artigo 1: *Assessment of safety and feasibility of a new technical variant of gastropexy for percutaneous endoscopic gastrostomy: an experience with 435 cases*
Paulo MO Campoli, Daniela MM Cardoso, Marília D Turchi, Flávio H Ejima, Orlando M Mota
BMC Gastroenterology 2009 (Publicado)

Artigo 2: *Peristomal infection in percutaneous endoscopic gastrostomy (PEG): a comparative study of two gastropexy techniques in a before-and-after design*
Paulo MO Campoli, Daniela MM Cardoso, Marília D Turchi, Flávio H Ejima, Orlando M Mota
Acta Gastroenterológica Latinoamericana (Submetido)

Artigo 3: *Clinical trial: a randomized study comparing the durability of silicone and latex percutaneous endoscopic gastrostomy (PEG) tubes*
Paulo MO Campoli, Daniela MM Cardoso, Marília D Turchi, Orlando M Mota
Digestive Endoscopy (Publicado)

Artigo 4: *Meta-analysis: Effect of the Introducer Technique compared with the Pull Technique on peristomal infection rate in percutaneous endoscopic gastrostomy*
Paulo MO Campoli, Adriano AP de Paula, Luana G Alves, Marília D Turchi
Endoscopy (Submetido)

BMC Gastroenterology

Research article

Open Access

Assessment of safety and feasibility of a new technical variant of gastropexy for percutaneous endoscopic gastrostomy: an experience with 435 cases

Paulo MO Campoli*[1,2], Daniela MM Cardoso[1], Marília D Turchi[3], Flávio H Ejima[1] and Orlando M Mota[2]

Address: [1]Department of Digestive Endoscopy, Araújo Jorge Hospital, Goiás Anticancer Association, Goiânia, GO, Brazil, [2]Department of Gastrointestinal Oncology, Araújo Jorge Hospital, Goiás Anticancer Association, Goiânia, GO, Brazil and [3]Department of Community Health, Institute of Tropical Pathology and Public Health, Federal University of Goiás, Goiânia, GO, Brazil

Email: Paulo MO Campoli* - paulomar@ih.com.br; Daniela MM Cardoso - danielamilhomem@terra.com.br; Marília D Turchi - mturchi@iptsp.ufg.br; Flávio H Ejima - ejima@terra.com.br; Orlando M Mota - omilhomem@terra.com.br

* Corresponding author

Published: 26 June 2009

BMC Gastroenterology 2009, **9**:48 doi:10.1186/1471-230X-9-48

Received: 19 January 2009
Accepted: 26 June 2009

This article is available from: http://www.biomedcentral.com/1471-230X/9/48

Abstract

Background: Percutaneous Endoscopic Gastrostomy (PEG) performed through the Introducer Technique is associated with lower risk of surgical infection when compared to the Pull Technique. Its use is less widespread as the fixation of the stomach to the abdominal wall is a stage of the procedure that is difficult to be performed. We present a new technical variant of gastropexy which is fast and easy to be performed. The aim of this study was to evaluate the safety and feasibility of a new technical variant of gastropexy in patients submitted to gastrostomy performed through the Introducer Technique.

Methods: All the patients submitted to PEG through the Introducer Technique were evaluated using a new technical variant of gastropexy, which consists of two parallel stitches of trasfixation sutures involving the abdominal wall and the gastric wall, performed with a long curved needle.

Prophylactic antibiotics were not used. Demographic aspects, initial diagnosis, indication, sedation doses, morbidity and surgical mortality were all analyzed.

Results: Four hundred and thirty-five consecutive PEGs performed between June 2004 and May 2007 were studied. Nearly all the cases consisted of patients presenting malignant neoplasia, 79.5% of which sited in the head and neck. The main indication of PEG was dysphagia, found in 346 patients (79.5%). There were 12 complications (2.8%) in 11 patients, from which only one patient had peristomal infection (0.2%). There was one death related to the procedure.

Conclusion: Gastropexy with the technical variant described here is easy to be performed and was feasible and safe in the present study. PEG performed by the Introducer Technique with this type of gastropexy was associated with low rates of wound infection even without the use of prophylactic antibiotics.

Background

Percutaneous Endoscopic Gastrostomy (PEG), described in 1980 [1,2], has replaced Conventional Surgical Gastrostomy as it has proved to be more advantageous. Its use, therefore, has grown rapidly in daily clinical practice [3].

Several technical variants have been described for performing PEG, with the one proposed by Gauderer et al [1] topping the list in the majority of centers. Known as the Pull Technique, it is easy to be performed and quite safe. Through this technique, the gastric tube (G-tube) is pulled through the mouth and the esophagus, which results in an increased risk of peristomal infection [4,5], despite the routine use of antibiotic prophylaxis, as is the risk of tumoral implantation in the surgical wound in patients presenting malignant tumors [6].

There is a technical variant, named the Introducer Technique, in which the G-tube is introduced by means of percutaneous punction in an attempt to avoid its passage through the mouth. It can be performed under radiological [7] or endoscopic [2,8-13] guidance and also offers the great advantage of low risk of peristomal infection, which renders the use of prophylactic antibiotics unnecessary [7,8,14]. This technique is also associated with low risk of tumor wound implantation [15]. A lower risk of infection and lower risk of tumor implantation has motivated several authors to use the Introducer Technique instead of using the Pull Technique for PEG [4,6,8,15,16].

The Introducer Technique almost always involves a stage in which the stomach is fixated to the abdominal wall (gastropexy). For such fixation, T-fasteners [7,16,17], Fogarty catheters [18] or stitches [2,5,8-11,14,19,20] can be used. The use of stitches was first described by Hashiba in 1980 [2]. In 1999, Kiser et al [10] reported gastropexy performed with two straight needles, a method used by us until June 2004 [8]. Several authors [5,9,11,14,20] have recently described the use of a device that also contains two straight needles for the easier performance of gastropexy.

We have recently published a successful series of 142 cases [8] of PEGs with an Introducer Technique variant which employs stitches with straight needles in order to fixate the anterior gastric wall to the abdominal wall, followed by the introduction of a G-tube by means of a percutaneous punction.

The present study describes a new technical variant of gastropexy which uses a long curved needle. It aims to investigate the feasibility and safety of the procedure.

Methods

Patients

We studied all patients referred to perform PEG in a tertiary cancer hospital between June 2004 and May 2007.

Exclusion criteria comprised patients with Body Mass Index (BMI) ≥ 30 kg/m^2, those on whom PEG was performed without gastropexy once the stomach was adequately fixated to the abdominal wall as well as those on whom PEG could not be performed.

Almost all the procedures were performed in the endoscopy room, with patients under conscious sedation and monitored by a pulse oximeter. Supplementary oxygen was used when necessary. Olympus GIF-V video gastroscope and Olympus CV-100 video processor were used (Olympus America Inc., Melville, New York, USA). All the procedures were performed by three authors specialized in digestive endoscopy and with experience in interventional endoscopic techniques.

Endoscopic dilation was attempted when stenosis was present and whenever possible performed with Eder-Puestow dilators. Prophylactic antibiotics were not used. All the patients were fed through the G-tube on the same day of the procedure.

An informed consent was obtained from all patients and this study was approved by the Ethical Institutional Review Board.

Suture method

Following a thorough endoscopic examination, the patient was placed in the supine position with upper limbs restraint. The insertion point was identified by transillumination and palpation of the abdominal wall. By using an aseptic technique along with lidocaine-induced local anesthesia, a stitch was employed involving the abdominal wall and the anterior gastric wall under endoscopic guidance (Figures 1a, b and 1c). A 7.6 cm-long needle of 1/2 circle curvature and polypropylene thread was used (B. Braun Medical Products, Aesculap Division, Tuttlingen, Germany). This same procedure was repeated and another U-shaped stitch was used parallel to the first stitch (Figure 1d). These two stitches provided the fixation of the anterior stomach wall on the abdominal wall.

Gastric tube introduction technique

Abdominal Wall Path

A cutaneous incision between the two stitches was performed, under local anesthesia with lidocaine (Figure 2a) and a tissue dissection with surgical scissors was made in order to reach the gastric wall without perforate it (Figure 2b).

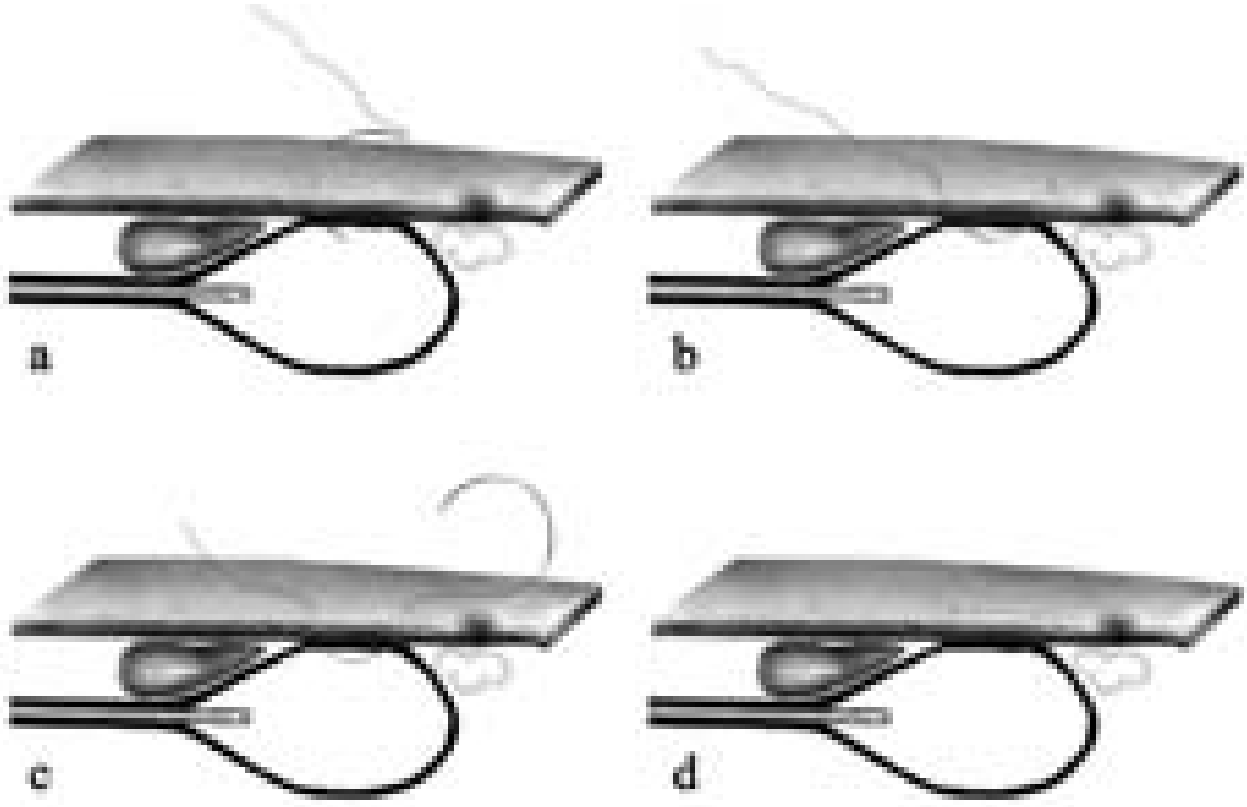


Figure 1
Suture method. Transfixation suture with curved needle involving the abdominal and the gastric wall, performed under endoscopic guidance (Figures 1a, b and 1c). A second transfixation U-shaped stitch was employed in parallel with the first one (Figure 1d).

Trocar Puncture

A metal trocar proper designed for PEG was used. A trocar puncture was performed through the path in order to reach the gastric cavity (Figure 3a). The trocar was removed and an external metal sheath with a longitudinal fenestration stayed in the path (Figure 3b).

Gastric Tube Introduction

A G-tube (16 Fr) was introduced through the sheath (Figure 3c) and the balloon was inflated (Figure 3d). The sheath was removed and disconnected from the G-tube through the longitudinal fenestration (Figure 3d).

Video

Watch the video containing the described procedure. [see Additional file 1].

Follow up

The patients received daily dry dressing and the gastropexy stitches were removed between postoperative days 10 and 12. The G-tube removal or changing was performed whenever needed. Wound infection evaluation was provided in all cases.

Analyzed parameters

The feasibility of the procedure was evaluated through the percentage of success in the performance of gastropexy among the cases included in the study.

To evaluate the safety of the method the complications were classified into two categories: minor and major complications. Minor complications were the ones which occurred during the procedure and were solved with no need of additional intervention. The major complications needed additional interventions or added risk to the patients. The safety was also evaluated by procedure related mortality.

Results

Patients' profile

During 36 months 515 patients were referred to the Endoscopy Unit to have PEG and 44 were excluded from

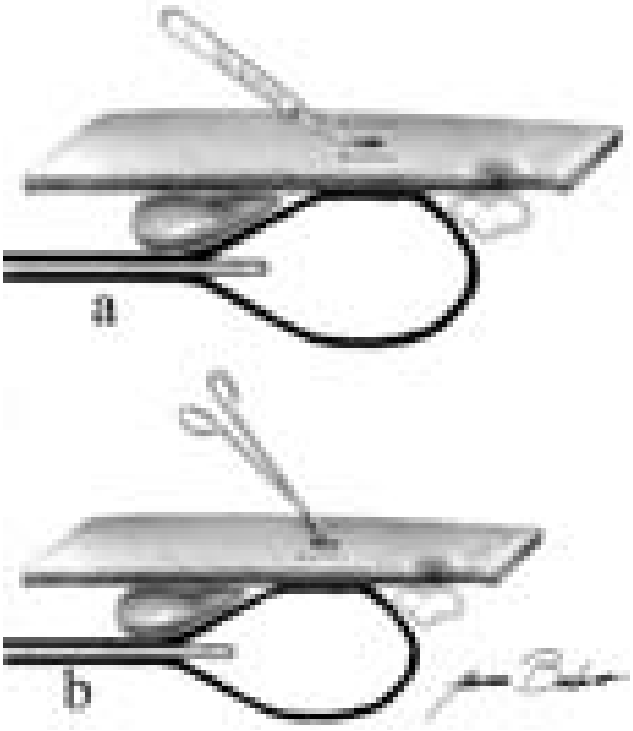


Figure 2
Gastric tube introduction technique – abdominal wall path. A cutaneous incision was made between the two stitches (Figure. 2a) and afterwards a path was made through the abdominal wall by using Metzenbaum scissors without puncturing the gastric wall (Figure. 2b).

the present study. The main reason for not performing this procedure was non dilatable stenosis (Table 1).

Among the 435 patients where curved needle gastropexy was performed (Figure 4), a clear predominance of the male gender was observed (4.4:1) and the mean age was 58.8 (8 – 99 years old). The vast majority of patients had malignant neoplasias with predominance of head and neck tumors (79.5%), followed by esophagus tumors (17.0%) and lung tumors (2.1%). Only six patients presented neurological disorders (Table 2). The main indication for the procedure was dysphagia in 346 patients (79.5%), followed by other indications listed in Table 2.

In four patients the procedure had to be performed under general anesthesia in the surgery room. In the other patients the PEG was performed in the endoscopy room and the conscious sedation was obtained with doses of midazolam ranging from 0 to 13 mg with a median of 4 mg (interquartile range, 3–5) associated or not with doses between 0 and 130 mg with a median of 40 mg (interquartile range, 30–50) of meperidine.

In 37 patients peptic ulcer was diagnosed (gastric or duodenal). Successful endoscopic dilation was performed in 24 patients. Nine patients were diagnosed as having a second synchronous neoplasia during the performance of PEG. Four patients had tracheoesophageal fistula. Two patients had previous partial gastrectomy.

Feasibility Evaluation

Among the 471 patients included, gastropexy was not performed in 36 of them through the method described in this study as the curved needles were unable to reach the gastric cavity due to excessively thick abdominal walls. In this group of patients, gastropexy was performed with two straight needles.

The remaining four hundred and thirty five suture-based PEGs were performed with the new curved-needle method described, representing a success index of 92.4% (Figure 4).

Safety Evaluation

Among the 435 patients in whom gastropexy was performed with a curved needle, morbidity consisted of 12 events (2.8%) in 11 patients. Minor complications occurred in 7 patients and consisted of four cases of gastric wall bleeding which were observed during the procedure and controlled with local measures and three cases of respiratory failure controlled with the habitual measures of ventilatory assistance and the use of naloxone or flumazenil.

Five major complications occurred in four patients. Section of the gastric wall caused by the thread of the first stitch occurred in one patient and resulted in pneumoperitoneum. Laparotomy was necessary to conclude the gastrostomy. The second patient started with abdominal pain on the postoperative period and a large pneumoperitoneum was identified. This patient underwent surgery with no other findings. The third patient evolved with a gastrocutaneous fistula closed after changing the G-tube for a Dobbhoff tube. The fourth patient presented wound infection (0.2%) on the first postoperative week. This patient received oral antibiotic with good outcome and resolution of the infection. This same patient developed wound leakage on postoperative day 50 due to severe malnutrition and cancer cachexia and died. There were one procedure-related death (0.2%), as described above.

Discussion

This study presents a high success rate of a simple and safe technical variant of the gastropexy during PEG, in patients with malignant diseases. Moreover, in this study this procedure was associated with a low surgical infection rate.

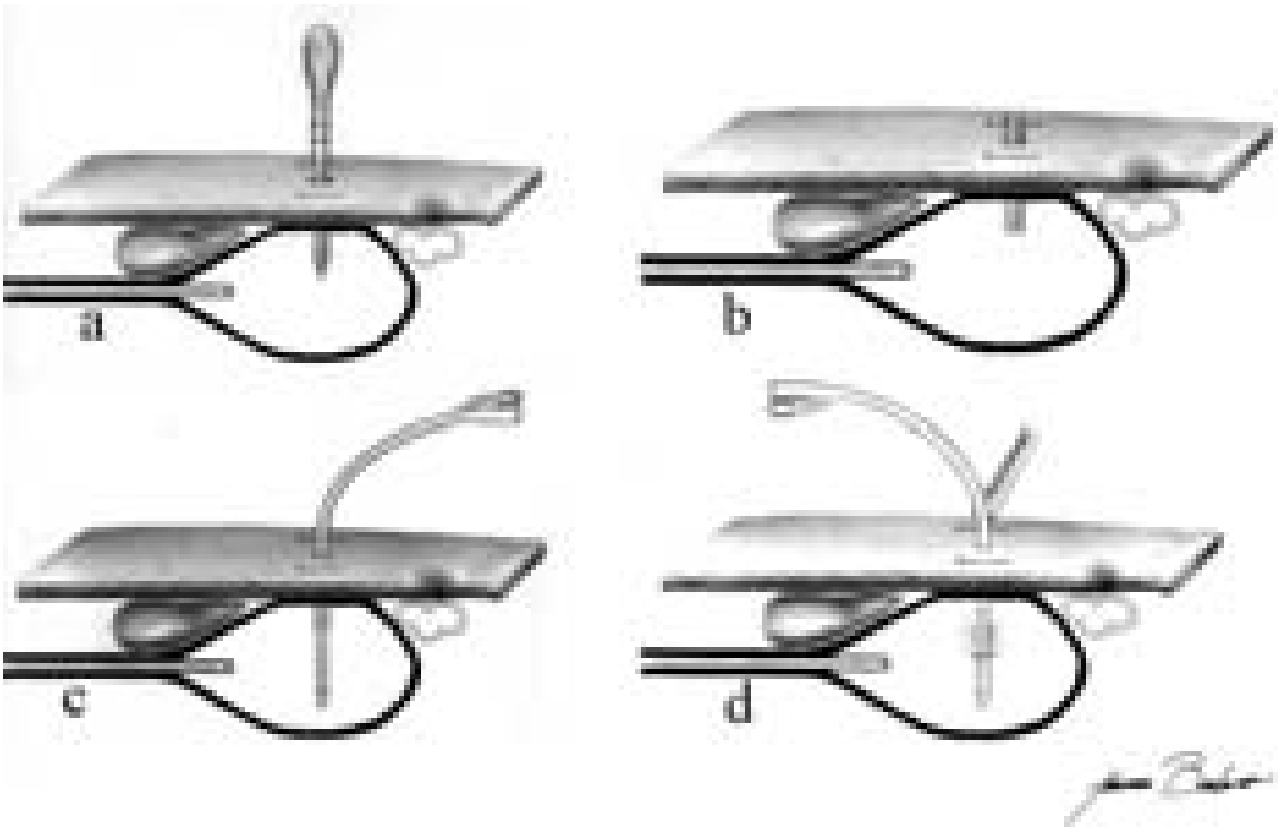


Figure 3
Gastric tube introduction technique – trocar puncture and gastric tube introduction. The gastric wall was punctured with a trocar introducer with a peel-away sheath (Figure. 3a and 3b), the G-tube was introduced through the sheath (Figure. 3c), the balloon was then inflated and the sheath was removed (Figure. 3d).

The low wound infection rate is the great advantage of the Introducer Technique. Pull Technique PEG performed with antibiotic prophylaxis has wound infection rates around 8% [21,22]. On the other hand, the series already published which used the Introducer Technique are presented in Table 3 and the pooled of available studies shows an infection rate of 1.4% (ranging from 0 to 3.6%).

Table 1: Exclusion criteria from the present study of 44 patients referred to the Endoscopy Unit to perform PEG*.

Causes	number	%
BMI ≥ 30 kg/m²**	3	6.8
PEGs suture-free technique	6	13.6
PEGs could not be performed		
Non dilatable stenosis	26	59.1
Neoplasias affecting stomach	3	6.8
Gastric ulcer perforation	2	4.5
Patients with ascites	2	4.5
Partial gastrectomy	1	2.3
Respiratory failure associated to supine position	1	2.3

*PEG, Percutaneous Endoscopic Gastrostomy
**BMI, Body Mass Index

The cases presented here were performed using this Introducer Technique, and even without using the prophylactic antibiotics, the peristomal infection rate was as low as 0.2%.

There are few studies comparing Pull Technique and Introducer Technique.

Three non-randomized studies with a small number of cases have compared the Pull Technique with the Introducer Technique. Deitel et al [23] reported that the Introducer Technique was not associated with peristomal infection, whereas Tucker et al [16] concluded that the risk of complications was significantly lower with this technique. The third study published recently showed that the Introducer Technique was associated with lower risk of peristomal infection, lower risk of aspiration pneumonia and lower postoperative hospital stay [20].

Table 2: Clinical features and morbimortality of 435 patients submitted to PEG* with curved needle.

Variable	number	%
Gender		
Male	354	81.4
Female	81	18.6
Baseline disease		
Head/Neck neoplasia	346	79.5
Esophagus neoplasia	74	17.0
Lung neoplasia	9	2.1
Neurologic disease	6	1.4
Indication		
Dysphagia	346	79.5
Preoperative	57	13.1
Salivary fistula	22	5.1
Nasal regurgitation	10	2.3
Minor complications		
Bleeding	4	0.9
Respiratory failure	3	0.7
Major complications		
Pneumoperitoneum	2	0.5
Leakage	2	0.5
Wound infection	1	0.2
Mortality	1	0.2

*PEG, Percutaneous Endoscopic Gastrostomy

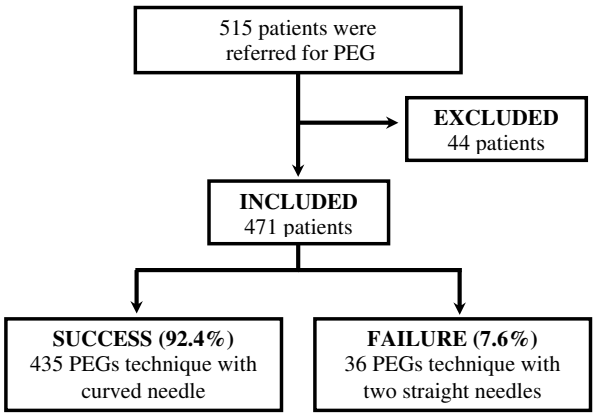


Figure 4
Distribution of patients referred for PEG.

Two studies that compared the two techniques through a prospective and randomized trials were lead by Maetani et al [4] and Horiuchi et al [5]. They found that the risk of peristomal infection was lower when the Introducer Technique was used.

In the present study major and minor complications occurred in a small number of cases with few repercussions for patients, yielding a morbidity rate of 2.8% and an acceptable mortality rate of 0.2%. We have a historical control group [8] in which gastropexy was performed with two straight needles in 142 patients and the morbidity rate was 9.1% and the mortality was 0.7%. Most authors use device with two straight needles upon the performance of gastropexy [5,9,11,14,20] and described a morbidity ranging from 0 to 6.7% and a mortality rate varied from 0 to 2.9%. The results of our study support the premise that gastropexy performed with curved needles is a safe procedure. Gastropexy as presented here is a more simple option which is easy to perform and uses surgical suture material routinely available in the surgical room.

The technical variant presented here is also feasible because a high success index was obtained (92.4%). The majority of failure procedures were due to not reaching the gastric cavity with the curved needles, and these situations were solved with the use of straight needles as described in other study [8].

One limitation of the present study is that feasibility and safety were not evaluated in relation to a control group in which gastropexy would be performed with two straight needles. Another limitation is that the population studied was almost entirely composed of patients with malignant neoplasias and BMI < 30 kg/m^2 and the validity of the method in populations with neurological diseases and different BMI profiles needs to be evaluated. Another disadvantage of this new technical variant of gastropexy is that it can only be used in patients evaluated by endoscopy.

Conclusion

The new gastropexy technical variant presented in this study has proven to be feasible and safe. This technique yielded low rates of peristomal infection and made unnecessary the use of prophylactic antibiotics.

List of abbreviations

PEG: Percutaneous Endoscopic Gastrostomy; G-tube: gastric tube; BMI: Body Mass Index.

Table 3: Published series of PEGs by the Introducer Technique

Author [ref]	Year	Gastropexy	Antibiotics	N	Infection (N)	Infection (%)
Russell TR [12]	1984	No	N/A	28	1	3.6
Hashiba K [19]	1987	Suture	N/A	56	0	0.0
Kadota T [13]	1991	No	N/A	89	3	3.4
Robertson FM [18]	1996	Fogarty	Yes	20	0	0.0
Tucker AT [16]	2003	T-fastener	Yes	29	0	0.0
Maetani I [4]	2003	No	Yes	29	0	0.0
Dormann AJ [9]	2006	Suture	Yes	46	1	2.2
Saito M [11]	2007	Suture	N/A	82	0	0.0
Campoli PMO [8]	2007	Suture	No	142	4	2.8
Toyama Y [20]	2007	Suture	Yes	30	1	3.3
Foster JM [17]	2007	T-fastener	No	149	5	3.4
Shastri YM [14]	2008	Suture	Yes	47	1	2.1
Shastri YM [14]	2008	Suture	No	46	1	2.2
Horiuchi A [5]	2008	Suture	Yes	68	0	0.0
Current series	2008	Suture	No	435	1	0.2
Pooled				**1,296**	**18**	**1.4 [95%CI: 0.9–2.2]**

N/A, information not available
CI, Confidence Interval

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

PMOC conceived the study, participated in its coordination and prepared the manuscript. DMMC contributed to conception and design, acquisition, analysis and interpretation of data, drafted and revised the manuscript. MDT did epidemiological assistance in analysis and interpretation of data results and helped to write the manuscript. FHE contributed to conception and design, drafted and revised the manuscript. OMM contributed to conception and design, drafted and revised the manuscript. All authors read and approved the final manuscript.

Additional material

Additional file 1

New technical variant of gastropexy for percutaneous endoscopic gastrostomy. *Video containing the described procedure.*
Click here for file
[http://www.biomedcentral.com/content/supplementary/1471-230X-9-48-S1.mpg]

References

1. Gauderer MW, Ponsky JL, Izant RJ Jr: **Gastrostomy without laparotomy: a percutaneous endoscopic technique.** *J Pediatr Surg* 1980, **15(6):**872-875.
2. Hashiba K: **[Technic for opening a gastrostomy under endoscopic control and manipulation].** *Rev Paul Med* 1980, **95(1–2):**37-38.
3. Gauderer MW: **Percutaneous endoscopic gastrostomy and the evolution of contemporary long-term enteral access.** *Clin Nutr* 2002, **21(2):**103-110.
4. Maetani I, Tada T, Ukita T, Inoue H, Sakai Y, Yoshikawa M: **PEG with introducer or pull method: a prospective randomized comparison.** *Gastrointest Endosc* 2003, **57(7):**837-841.
5. Horiuchi A, Nakayama Y, Tanaka N, Fujii H, Kajiyama M: **Prospective randomized trial comparing the direct method using a 24 Fr bumper-button-type device with the pull method for percutaneous endoscopic gastrostomy.** *Endoscopy* 2008, **40(9):**722-726.
6. Cappell MS: **Risk factors and risk reduction of malignant seeding of the percutaneous endoscopic gastrostomy track from pharyngoesophageal malignancy: a review of all 44 known reported cases.** *Am J Gastroenterol* 2007, **102(6):**1307-1311.
7. Dinkel HP, Beer KT, Zbaren P, Triller J: **Establishing radiological percutaneous gastrostomy with balloon-retained tubes as an alternative to endoscopic and surgical gastrostomy in patients with tumours of the head and neck or oesophagus.** *Br J Radiol* 2002, **75(892):**371-377.
8. Campoli PMO, Ejima FH, Cardoso DMM, Barros AP Jr, Souza Fo PP, Freitas MAF, Castro FCF, Barreto PAQ, Mota OM: **[Percutaneous endoscopic gastrostomy performed using the suture and percutaneous puncture technique].** *GED – Gastroenterologia Endoscopia Digestiva* 2007, **26(4):**109-113. Current url: http://www.fbg.org.br/medicos/associado/conteudo_cientifico/revistas/ged/_revistas/gedv26n4-109-113.pdf
9. Dormann AJ, Wejda B, Kahl S, Huchzermeyer H, Ebert MP, Malfertheiner P: **Long-term results with a new introducer method with gastropexy for percutaneous endoscopic gastrostomy.** *Am J Gastroenterol* 2006, **101(6):**1229-1234.
10. Kiser AC, Inglis G, Nakayama DK: **Primary percutaneous endoscopic button gastrostomy: a modification of the "push" technique.** *J Am Coll Surg* 1999, **188(6):**704-706.
11. Saito M, Muto M, Yano T, Kojima T, Minashi K, Ohtsu A, Yoshida S: **Gastropexy Reduces Severe Adverse Events After Percutaneous Endoscopic Gastrostomy (PEG).** *Gastrointest Endosc* 2007, **65(5):**AB163.
12. Russell TR, Brotman M, Norris F: **Percutaneous gastrostomy. A new simplified and cost-effective technique.** *Am J Surg* 1984, **148(1):**132-137.

13. Kadota T, Nakagawa K, Taguchi J, Ono H, Hiraide H, Tamakuma S, Ueno F: **A simplified percutaneous endoscopic gastrostomy using the trocar introducer technique with peel-away sheath.** *Surg Gynecol Obstet* 1991, **173(6):**490-494.
14. Shastri YM, Hoepffner N, Tessmer A, Ackermann H, Schroeder O, Stein J: **New introducer PEG gastropexy does not require prophylactic antibiotics: multicenter prospective randomized double-blind placebo-controlled study.** *Gastrointest Endosc* 2008, **67(4):**620-628.
15. Cruz I, Mamel JJ, Brady PG, Cass-Garcia M: **Incidence of abdominal wall metastasis complicating PEG tube placement in untreated head and neck cancer.** *Gastrointest Endosc* 2005, **62(5):**708-711. quiz 752, 753
16. Tucker AT, Gourin CG, Ghegan MD, Porubsky ES, Martindale RG, Terris DJ: **'Push' versus 'pull' percutaneous endoscopic gastrostomy tube placement in patients with advanced head and neck cancer.** *Laryngoscope* 2003, **113(11):**1898-1902.
17. Foster JM, Filocamo P, Nava H, Schiff M, Hicks W, Rigual N, Smith J, Loree T, Gibbs JF: **The introducer technique is the optimal method for placing percutaneous endoscopic gastrostomy tubes in head and neck cancer patients.** *Surg Endosc* 2007, **21(6):**897-901.
18. Robertson FM, Crombleholme TM, Latchaw LA, Jacir NN: **Modification of the "push" technique for percutaneous endoscopic gastrostomy in infants and children.** *J Am Coll Surg* 1996, **182(3):**215-218.
19. Hashiba K: **Endoscopic gastrostomy.** *Endoscopy* 1987, **1(Suppl 1):**23-24.
20. Toyama Y, Usuba T, Son K, Yoshida S, Miyake R, Ito R, Tsuboi K, Kashiwagi H, Tajiri H, Yanaga K: **Successful new method of extracorporeal percutaneous endoscopic gastrostomy (E-PEG).** *Surg Endosc* 2007, **21(11):**2034-2038.
21. Jafri NS, Mahid SS, Minor KS, Idstein SR, Hornung CA, Galandiuk S: **Meta-analysis: antibiotic prophylaxis to prevent peristomal infection following percutaneous endoscopic gastrostomy.** *Aliment Pharmacol Ther* 2007, **25(6):**647-656.
22. Lipp A, Lusardi G: **Systemic antimicrobial prophylaxis for percutaneous endoscopic gastrostomy.** *Cochrane Database Syst Rev* 2006:CD005571.
23. Deitel M, Bendago M, Spratt EH, Burul CJ, To TB: **Percutaneous endoscopic gastrostomy by the "pull" and "introducer" methods.** *Can J Surg* 1988, **31(2):**102-104.

Pre-publication history

The pre-publication history for this paper can be accessed here:

http://www.biomedcentral.com/1471-230X/9/48/prepub

Peristomal infection in percutaneous endoscopic gastrostomy (PEG): a comparative study of two gastropexy techniques in a before-and-after design

Summary

Introduction: Percutaneous endoscopic gastrostomy (PEG) performed using the Pull technique is associated with a high rate of surgical infections. When PEG is performed using the Introducer technique, a lower rate of infection is seen. However, this technique can pose technical difficulties during gastropexy. Gastropexy using two straight needles, our initial method, causes the snare to be in contact with the sterile suture. We have recently used an original gastropexy technique performed with a long curved needle in which there is no contamination of the sterile suture. The aim of this study is to compare the rates of infection observed with these two methods of gastropexy.

Methods: The Introducer technique was performed in all patients with two different gastropexy techniques used during two separate, consecutive periods. Antibiotic prophylaxis was not used during either procedure. Any surgical infections were treated with local wound care and/or antibiotic therapy with treatment based on the severity of the infection. The surgical infection rates in each group were compared.

Results: Group I consisted of 142 patients who underwent gastropexy with two straight needles, and Group II consisted of 435 patients on whom gastropexy was performed with a curved needle. The infection rates found in Groups I and II were 2.8% and 0.2%, respectively (p=0.03).

Conclusions: Gastropexy performed with a curved needle was associated with a lower rate of infection when compared to gastropexy performed with two straight needles.

Introduction

Percutaneous endoscopic gastrostomy (PEG), first described in 1980 by two independent centers,[1, 2] is currently the safest and most common way of performing a gastrostomy. According to the technique proposed by Hashiba[1] (known as the Introducer technique), the gastrostomy tube is inserted directly into the stomach and involves a stage in which the stomach is fixated to the abdominal wall (gastropexy). This technique failed to gain popularity, however, likely due to its technical complexity.

In contrast, the procedure proposed by Gauderer et al.[2] gained wide acceptance because it is easy to perform and results in good outcomes.[3] Despite its suitability, Gauderer's technique (known as the Pull technique), is less than optimal in that the gastrostomy tube is pulled through the mouth, resulting in a high risk of peristomal infections. If antibiotics are administered, the rate of surgical infection associated with this technique is 8.7%; however, the rate can be as high as 26% if antibiotic prophylaxis is not used.[4, 5] In addition, Gauderer's technique is associated with a non-negligible risk of tumor implantation at the surgical site in patients with esophageal or head and neck cancers.[6]

Hashiba's Introducer technique,[1] has undergone several important changes that have made the procedure easier to perform.[7-12] The Introducer technique has several advantages, including its low risk of infection and the fact that it does not put patients with malignant neoplasia at risk of tumor implantation.[6] In our institution, a large cancer center, the Introducer technique for gastrostomy has been used since 2003, because the majority of our patients needing a gastrostomy have malignant neoplasia. More than 500 PEG using two straight needles or long curved needle for fixation of the stomach to the abdominal wall have been performed at our institution, in a five years period. The present study compares the rates of surgical infection between these two methods of gastropexy in an oncology center in Brazil.

Patients and methods

Consecutive patients who underwent successful PEG placement between 2003 and 2007 were enrolled. Informed consent was obtained from all patients, and the study was approved by the Ethical Institutional Review Board. The Introducer technique was performed on all patients, and two different methods of gastropexy were used during two separate, consecutive periods.

From February 2003 to July 2004, 142 patients (Group I) underwent PEG with fixation of the stomach to the abdominal wall performed using a technical variant[13] of the method proposed by Kiser et al.[14] This method uses two straight needles (Figure 1), and the technical variant requires the snare to be in contact with the sterile suture. One of the needles has a strand of 2-0 nylon suture and the other has a loop made with the nylon suture (Figure 1a). A polypectomy snare is used to bring the loose suture into the interior of the loop (Figures 1b and 1c). After appropriate capture, the whole set is taken out so as to obtain a U-shaped suture (Figures 1d and 1e). Additional technical details on this series of cases have been described elsewhere.[13] Despite being difficult to perform, this method produces good results.

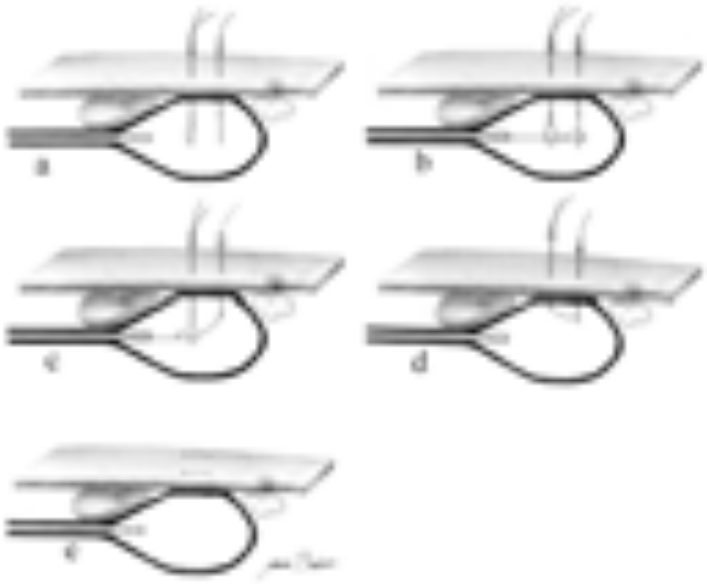


Figure 1. Suture method. Two long needles were used to puncture the gastric wall (Figure 1a). The loose suture was attached by the snare (Figure 1b) and brought into the loop (Figure 1c). The loose suture was held by the loop and brought back to the skin (Figure 1d) in order to make a transfixion stitch in the form of a “U”. This procedure was repeated to make another stitch next to the first one (Figure 1e).

From June 2004 to May 2007, 435 patients (Group II) underwent PEG with gastropexy performed using a long curved needle to place two suture stitches, which transfix the abdominal and gastric walls (Figure 2). For this procedure, patients with a body mass index (BMI) $\geq$ 30 kg/m^2 were excluded. In addition to being easier to perform, this technical variant does not require contact of the sterile suture with any endoscopic accessory. A previously published study on the safety and feasibility of this technique for gastropexy during PEG demonstrated remarkably low infection rates.[15]

Figure 2. Suture method. Transfixation suture using a curved needle for the abdominal and gastric walls, performed under endoscopic guidance (Figures 2a, 2b, and 2c). A second transfixation U-shaped stitch was placed parallel to the first stitch(Figure 2d).

The remainder of the procedure was performed using the Introducer technique. The balloon gastrostomy tube was positioned with the help of a metal trocar (Figures 3 and 4). Neither group received antibiotic prophylaxis. Dressings were changed daily until 10 to 12 days postoperatively, when the stitches were removed. Surgical site infections were treated with local care and antibiotics, based on the severity of the infection.

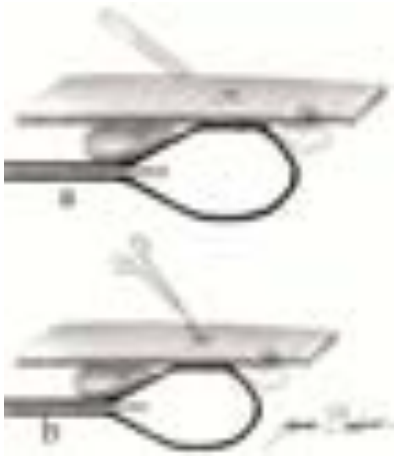


Figure 3. Gastric tube introduction technique, abdominal wall path. A cutaneous incision was made between the two stitches (Figure 3a), and afterwards a path was made through the abdominal wall by using Metzenbaum scissors without puncturing the gastric wall (Figure 3b).

Figure 4. Gastric tube introduction technique, trocar puncture and gastric tube introduction. The gastric wall was punctured with a trocar introducer with a peel-away sheath (Figures 4a and 4b). The G-tube was introduced through the sheath (Figure 4c); the balloon was then inflated, and the sheath was removed (Figure 4d).

Either Yates-corrected chi-square or Fisher exact tests, whichever was deemed the most appropriate, were used to compare categorical variables. Continuous variables were compared using Student t-test. All analyses were two-tailed. P values less than 0.05 were considered to be significant.

Results

Of the 577 patients, 568 (98%) had a malignancy, mainly esophageal or head and neck cancers. The ratio of male to female patients was 4.2:1. The majority of procedures were performed in the digestive endoscopy room, under conscious sedation and monitored with pulse oximetry. Of the 577 patients, 166 (28.8%) underwent the procedure on an outpatient basis.

Table 1 shows the baseline characteristics of the two groups. There were no significant differences between the two groups regarding the sex or age of the patients or in the indications for the procedure. However, the percentage of patients with head and neck tumors was significantly higher in Group II compared with Group I. The main findings on endoscopy were stenosis, active peptic ulcer, and tracheoesophageal fistula; the differences in the frequency of these findings between the two groups did not reach statistical significance.

Table 1. Patient Baseline Characteristics.

Variable	Group I (n = 142)	Group II (n = 435)	p-value
Sex			
Male	113 (79.6%)	354 (81.4%)	p = 0.72
Female	29 (20.4%)	81 (18.6%)	
Age			
Mean (SD)	60.0 (12.71)	58.8 (12.42)	p = 0.32
Indication			
Dysphagia	111 (78.2%)	346 (79.5%)	p = 0.82
Others indications	31 (21.8%)	89 (20.5%)	
Baseline disease			
Head and neck cancer	98 (69.0%)	346 (79.5%)	p = 0.01
Esophageal cancer	33 (23.3%)	74 (17.0%)	p = 0.12
Others diseases	11 (7.7%)	15 (3.5%)	p = 0.06
Main endoscopic findings			
Stenosis	12 (8.4%)	24 (5.5%)	p = 0.29
Peptic ulcer	7 (4.9%)	37 (8.5%)	p = 0.23
Tracheoesophageal fistula	4 (2.8%)	4 (0.9%)	p = 0.21

Abbreviations: SD, standard deviation

Procedure-related morbidity was significantly lower in Group II than in Group I, primarily due to significantly lower risks of surgical site infection (odds ratio [OR]=0.08, 95% confidence interval [CI], 0.01-0.72; p=0.03) and respiratory depression (OR=0.16, 95%CI, 0.04-0.64; p=0.02) (Table 2). There was one procedure-related death in each group; however, the observed percent difference did not reach statistical significance.

Table 2. Rates of Morbidity and Mortality.

	Group I (n = 142)	Group II (n = 435)	p-value
Morbidity	13 (9.1%)	12 (2.8%)	p = 0.003
Surgical infection	4 (2.8%)	1 (0.2%)	p = 0.03
Respiratory depression	6 (4.2%)	3 (0.7%)	p = 0.02
Other	3 (2.1%)	8 (1.8%)	p = 0.99
Mortality	1 (0.7%)	1 (0.2%)	p = 0.86

Discussion

The present study suggests that gastropexy performed with a curved needle (Group II) was associated with lower morbidity when compared with gastropexy performed with two straight needles (Group I). Respiratory depression was the major complication and occurred in a significantly higher percentage of patients in Group I. In 3 of the 6 cases of respiratory depression in Group I, a tracheotomy was performed while the patient was still in the endoscopy room. These patients had a large tumor volume affecting the larynx and had a borderline need for tracheotomy prior to the procedure. Gibson et al.[16] described this complication and expressed the importance of identifying those patients already facing respiratory difficulties and referring them for tracheotomy before performing PEG. In the present study, the lower rate of respiratory depression among patients that underwent gastropexy with the use of curved needles (Group II) may be due to experience gained by the endoscopy team in identifying patients at risk and referring them for tracheotomy before performing PEG.

The overall surgical infection rate was low in both groups. These results were achieved without the use of antibiotic prophylaxis and are

consistent with rates reported elsewhere when PEG is performed using the Introducer technique.[10, 11, 17-19] In addition, the rates reported in our study were lower than those reported when PEG is performed using the Pull technique, even when antibiotic prophylaxis is used.[4, 5, 20]

When the rates of infection were compared between Groups I and II, the latter group had a significantly lower risk of surgical infection. The lower rate of surgical infection in Group II may be attributed to the gastropexy technique used. The absence of contact of endoscopic accessories with the sterile suture and the ease of performance of the procedure may be explanations for this lower rate of surgical infections in Group II. There is, however, the possibility that the lower infection rate achieved in Group II may be due to other, confounding factors not identified in this study.

Several authors who use the Introducer technique, both endoscopically[11, 21] and radiologically,[22] have deemed the use of antibiotic prophylaxis unnecessary. To the best of our knowledge, at the present, there is only one published randomized trial evaluating this issue with the Introducer technique.[19] In this trial, the authors did not find any difference in the infection rate between cases that received antibiotic prophylaxis (49 patients) and those that did not (48 patients). It must be noted, however, that this study had a low number of events and, therefore, may have had too low a power to detect a difference (i.e., a type II error). Randomized studies on the use of the Introducer technique that have an adequate number of patients are needed to determine if antibiotic prophylaxis is necessary.

The main limitation of the present study is that a comparison was made to a historic group (Group I), which consisted of patients undergoing PEG at the beginning of the learning process. Another potential limitation of this study is that obese patients were excluded from Group II, possibly resulting in an underestimation of infection rates in these patients. However, it is important to point out that only three patients (0.7%) were excluded from Group II because they had a BMI $\geq$ 30 kg/m^2.[15]

The results of this study are evidence that PEG with the Introducer technique is associated with lower infection rates than procedures using the technique proposed by Gauderer et al.[2] Furthermore, this study supports the

suggestion that antibiotic prophylaxis is unnecessary when the Introducer technique is used.

In conclusion, the present study suggests that gastropexy performed with the technique that uses a curved needle is associated with a lower rate of surgical infections when compared to the gastropexy technique that uses two straight needles.

References

1. Hashiba K. [Technic for opening a gastrostomy under endoscopic control and manipulation]. Rev Paul Med 1980;95:37-38.
2. Gauderer MW, Ponsky JL, Izant RJ, Jr. Gastrostomy without laparotomy: a percutaneous endoscopic technique. J Pediatr Surg 1980;15:872-875.
3. Gauderer MW. Percutaneous endoscopic gastrostomy and the evolution of contemporary long-term enteral access. Clin Nutr 2002;21:103-110.
4. Jafri NS, Mahid SS, Minor KS, Idstein SR, Hornung CA, Galandiuk S. Meta-analysis: antibiotic prophylaxis to prevent peristomal infection following percutaneous endoscopic gastrostomy. Aliment Pharmacol Ther 2007;25:647-656.
5. Lipp A, Lusardi G. Systemic antimicrobial prophylaxis for percutaneous endoscopic gastrostomy. Cochrane Database Syst Rev 2006:CD005571.
6. Cappell MS. Risk factors and risk reduction of malignant seeding of the percutaneous endoscopic gastrostomy track from pharyngoesophageal malignancy: a review of all 44 known reported cases. Am J Gastroenterol 2007;102:1307-1311.
7. Russell TR, Brotman M, Norris F. Percutaneous gastrostomy. A new simplified and cost-effective technique. Am J Surg 1984;148:132-137.
8. Dormann AJ, Glosemeyer R, Leistner U, Deppe H, Roggel R, Wigginghaus B, Huchzermeyer H. Modified percutaneous endoscopic gastrostomy (PEG) with gastropexy--early experience with a new introducer technique. Z Gastroenterol 2000;38:933-938.
9. Sabnis A, Liu R, Chand B, Ponsky J. SLiC technique. A novel approach to percutaneous gastrostomy. Surg Endosc 2006;20:256-262.
10. Toyama Y, Usuba T, Son K, Yoshida S, Miyake R, Ito R, Tsuboi K, Kashiwagi H, Tajiri H, Yanaga K. Successful new method of extracorporeal percutaneous endoscopic gastrostomy (E-PEG). Surg Endosc 2007;21:2034-2038.
11. Foster JM, Filocamo P, Nava H, Schiff M, Hicks W, Rigual N, Smith J, Loree T, Gibbs JF. The introducer technique is the optimal method for placing percutaneous endoscopic gastrostomy tubes in head and neck cancer patients. Surg Endosc 2007;21:897-901.
12. Terry NE, Boswell WC, Carney DE, Beck A, Lowe L, Rittmeyer C. Percutaneous endoscopic gastrostomy with T-bar fixation in children and infants. Surg Endosc 2008;22:167-170.

13. Campoli PM, Ejima FH, Cardoso DM, BarrosJr AP, SouzaFo PP, Freitas MAF, Castro FCF, Barreto PAQ, Mota OM. Percutaneous endoscopic gastrostomy performed using the suture and percutaneous puncture technique. GED Gastroenterologia Endoscopia Digestiva 2007;26:109-113.
14. Kiser AC, Inglis G, Nakayama DK. Primary percutaneous endoscopic button gastrostomy: a modification of the "push" technique. J Am Coll Surg 1999;188:704-706.
15. Campoli PM, Cardoso DM, Turchi MD, Ejima FH, Mota OM. Assessment of safety and feasibility of a new technical variant of gastropexy for percutaneous endoscopic gastrostomy: an experience with 435 cases. BMC Gastroenterol 2009;9:48.
16. Gibson SE, Wenig BL, Watkins JL. Complications of percutaneous endoscopic gastrostomy in head and neck cancer patients. Ann Otol Rhinol Laryngol 1992;101:46-50.
17. Dormann AJ, Wejda B, Kahl S, Huchzermeyer H, Ebert MP, Malfertheiner P. Long-term results with a new introducer method with gastropexy for percutaneous endoscopic gastrostomy. Am J Gastroenterol 2006;101:1229-1234.
18. Horiuchi A, Nakayama Y, Tanaka N, Fujii H, Kajiyama M. Prospective randomized trial comparing the direct method using a 24 Fr bumper-button-type device with the pull method for percutaneous endoscopic gastrostomy. Endoscopy 2008;40:722-726.
19. Shastri YM, Hoepffner N, Tessmer A, Ackermann H, Schroeder O, Stein J. New introducer PEG gastropexy does not require prophylactic antibiotics: multicenter prospective randomized double-blind placebo-controlled study. Gastrointest Endosc 2008;67:620-628.
20. Blomberg J, Lagergren P, Martin L, Mattsson F, Lagergren J. Novel approach to antibiotic prophylaxis in percutaneous endoscopic gastrostomy (PEG): randomised controlled trial. BMJ 2010;341:c3115.
21. Saunders JR, Jr., Brown MS, Hirata RM, Jaques DA. Percutaneous endoscopic gastrostomy in patients with head and neck malignancies. Am J Surg 1991;162:381-383.
22. Dinkel HP, Beer KT, Zbaren P, Triller J. Establishing radiological percutaneous gastrostomy with balloon-retained tubes as an alternative to endoscopic and surgical gastrostomy in patients with tumours of the head and neck or oesophagus. Br J Radiol 2002;75:371-377.

Digestive Endoscopy (2010) ••, ••–••

doi:10.1111/j.1443-1661.2010.01051.x

ORIGINAL ARTICLE

CLINICAL TRIAL: A RANDOMIZED STUDY COMPARING THE DURABILITY OF SILICONE AND LATEX PERCUTANEOUS ENDOSCOPIC GASTROSTOMY TUBES

Paulo Campoli,[1,2] Daniela Cardoso,[1] Marilia Turchi[2] and Orlando Mota[3]

[1]*Department of Gastrointestinal Endoscopy and* [3]*Gastrointestinal Surgery, Araujo Jorge Hospital, and* [2]*Institute of Tropical Pathology and Public Health, Federal University of Goias, Goias, Brazil*

Background: The use of percutaneous endoscopic gastrostomy (PEG) for nutrition support is increasing worldwide, but few studies have evaluated the durability of and complications related to the different materials used to manufacture gastrostomy tubes. Latex PEG tubes are widely used in our clinical setting, but no studies have compared their durability with silicone PEG tubes. The aim of the present study was to compare the durability of latex tubes with the durability of silicone tubes.

Patients and Methods: A randomized clinical trial was conducted in patients with head and neck cancer with indications for PEG. Sixty patients were randomized to receive either latex or silicone PEG tubes and followed up for 90 days. The analyzed outcomes were duration, peristomal infection, granulated tissue formation, and leakage around the tube.

Results: The durability of silicone PEG tubes was significantly greater than the durability of latex PEG tubes. The survival curves showed that silicone PEG tubes lasted twice as long (hazard ratio = 2.0, 95% confidence interval = 1.1–3.7, $P = 0.01$). No differences were found with regard to rate of peristomal infection, granulated tissue formation, or leakage.

Conclusion: Silicone PEG tubes are associated with a reduced need for replacement (attributable to higher durability) compared with latex PEG tubes.

Key words: biocompatible materials, nutrition therapy, percutaneous endoscopic gastrostomy.

INTRODUCTION

Since it was described in 1980,[1,2] the use of percutaneous endoscopic gastrostomy (PEG) has grown rapidly in daily clinical practice.[3] Among several technical variations of PEG, the one proposed by Gauderer *et al*. is the most widely used.[1] Named the Pull Technique, it is easy to perform and very safe. In this technique, however, the gastric tube is pulled through the mouth, resulting in an increased risk of peristomal infection,[4,5] despite the use of prophylactic antibiotics. The technique also has the risk of inadvertent tumor implantation in surgical wounds of patients with malignant tumors.[6]

Another variation of PEG is the Introducer Technique, in which the gastrostomy is performed by percutaneous puncture, avoiding the tube passage through the mouth. This technique is associated with a low risk of infection[7,8] and tumor implantation.[9] These advantages have motivated several authors to use the Introducer Technique rather than the Pull Technique.[4–6,8–10]

A large number of studies have investigated several PEG-related aspects. However, the literature regarding the durability of and the complications associated with gastrostomy tubes is sparse.[11,12] Gastrostomy tubes may be made of several different materials. The clinical and economic implications of tube durability, cost, and complications are important and should be investigated further. Only three published studies (one retrospective study[13] and two randomized studies[11,14]) have compared the durability and complications of silicone PEG tubes and polyurethane PEG tubes. None of the aforementioned randomized studies demonstrated differences in durability between these two types of tubes.

In our institution, PEG is successfully performed using the Introducer Technique[8] with a silicone-coated latex Foley tube. Despite its low cost, this is a short-lived tube, which demands frequent replacements. No studies have compared latex PEG tubes with pure silicone PEG tubes. We hypothesized that pure silicone PEG tubes would last longer than latex PEG tubes, and we designed the present comparative study to assess the differences in durability between these two materials. In addition, this study compared peristomal infection rate, granulated tissue formation, and leakage between the two types of tubes.

METHODS

Study design and randomization

We conducted this prospective, open-label, randomized clinical trial at an oncology reference center in Brazil. Randomization was based on a permuted blocks procedure using a computer-generated random number sequence with allocation concealment by sequentially numbered, sealed opaque envelopes. The allocation proportion was 1:1. The study

Correspondence: Paulo MO Campoli, Department of Gastrointestinal Endoscopy, Araujo Jorge Hospital, Avenida 85, Numero 300, Edificio Itatiaia, Setor Marista, 74160-010, Goiania-Goias, Brazil. Email: paulomar@ih.com.br

Received 11 March 2010; accepted 7 June 2010.

protocol was approved by the institutional review board, and written informed consent was obtained from all patients before enrollment in the study.

Patients

The inclusion criteria were patients aged 18 or older with head and neck cancer, an Eastern Cooperative Oncology Group (ECOG)[15] performance status score ≤2, a body mass index (BMI) ≤ 25 kg/m^2, and indication of gastrostomy for nutritional support. Patients who were unable to undergo PEG (trismus, partial gastrectomy, and non-dilatable stenosis) were excluded from the study.

Interventions

To achieve comparability, patients were randomized to receive either silicone-coated latex tubes (16 Fr Foley catheters; Medical Goldman, São José, SC, Brazil) or pure silicone tubes (14 Fr Gastrostomy Feeding Tube; Kimberly-Clark, Roswell, GA, USA). The type of tube was only disclosed upon the introduction of the tube during the PEG procedure. All of the procedures were performed in the endoscopy room, with patients under conscious sedation and monitored by a pulse oximeter. Prophylactic antibiotics were not administered. The Introducer Technique was used with all patients. Procedural details have been published elsewhere[8] and are available in full text and video at http://www.biomedcentral.com/1471-230X/9/48. Following the placement of the gastrostomy feeding tube, the patients were told to return for follow up after 7, 14, 28, 60, and 90 days.

Outcomes

The main outcome was the duration of the gastrostomy tube, measured from the date it was inserted until its first exchange or withdrawal for any reason. Such situations could occur under the following four conditions: the patient is alive with the tube *in situ*, the patient dies with a well-functioning tube, the patient regains the ability to eat by mouth, or the tube malfunctions by balloon deflation, obstruction, or deteriorated connection.

The secondary outcomes of the study were peristomal infection rate, granulated tissue formation, and leakage around the gastrostomy tube. The determination of peristomal infection was based on the description by Akkersdijk *et al*.[16] Mild infection was defined as hyperemia >20 mm in diameter with or without suppuration and severe infection in the case of systemic infection (fever or leukocytosis). Granulated tissue was defined as new connective tissue and fine blood vessels of any size surrounding the gastrostomy tube. Leakage was defined as any outflow of gastric fluids around the tube.

Statistical analysis

Sample size estimation was based on a study by Sartori *et al*.,[13] which reported the need to replace a malfunctioning silicone PEG tube in 38% of cases. Because of the lack of data regarding the durability of latex tubes, we estimated that latex tubes would present a malfunctioning rate that is twice as high as silicone tubes (relative risk [RR] = 2.0). We estimated that 60 patients (30 in each group) would be necessary to yield 80% power to detect significant durability differences with an alpha level of 0.05. Continuous variables are expressed as mean ± standard deviation (SD), and categorical variables are expressed as absolute numbers and percentages. Proportions were compared using the χ^2-test or Fisher's exact test, and continuous variables were analyzed using the Student's *t*-test. The cumulative risks of the primary outcome were estimated separately for each group using the Kaplan–Meier procedure[17] and were compared across groups using the log–rank test. Statistical analyses were performed using SPSS software, version 13.0 (SPSS, Chicago, IL, USA). The primary outcome events were measured from the date of PEG insertion to the date of replacement or removal of the tube. Observations were censored when the patient died or was lost to follow up.

RESULTS

Sixty patients were randomized, thirty in each group. The mean age at PEG insertion was 59.2 years (range, 39–85 years). The study population consisted of 83% men. Baseline characteristics are presented in Table 1. The two groups had similar characteristics ($P > 0.05$) with regard to age, gender, ECOG performance status, BMI, anatomical site, indication, active cancer, and enrollment setting (i.e. inpatient or outpatient).

Several forms of acid peptic disease were found during endoscopy, but they were evenly distributed across the two study groups. Only four cases experienced bleeding during the PEG procedure, all of which were managed with conservative measures. One case experienced respiratory failure, which was also managed with conservative measures. The duration of the surgical procedure ranged from 5 to 10 min, and the average duration was similar across the two study groups (Table 2).

With regard to the primary outcome, silicone PEG tubes showed higher durability compared with latex PEG tubes. Table 3 presents the mean duration in each group, which was significantly greater with silicone PEG tubes compared with latex tubes. Kaplan–Meier curves (Fig. 1) showed that the durability of the silicone PEG tubes was twice as high as the durability of the latex PEG tubes (hazard ratio [HR] = 2.0, 95% confidence interval = 1.1–3.7, $P = 0.01$). The median duration of the silicone PEG tubes was 88 days, which was higher than the median duration of the latex tubes (38 days). Some tubes were removed because of tube malfunctions (balloon deflation, obstruction or deteriorated connection) and an ad hoc analysis showed that 39 tubes were removed due to one of these reasons, which was evenly distributed across the two groups (silicone = 19, latex = 20). In this subgroup of tubes removed because of a malfunction, the mean duration of the silicone PEG tubes was 57.2 days (SD = 38.6) compared with only 31.8 days (SD = 26.5) for the latex tubes ($P = 0.02$).

None of the cases presented with severe infection. All of the cases of site infection were classified as mild infection. The number of cases of mild infection and granulated tissue at the surgical site was higher in the latex tube group than in the silicone tube group, but the difference was not statistically

Table 1. Baseline demographics and clinical characteristics of patients

	Latex ($n = 30$)		Silicone ($n = 30$)		P
Age in years, mean (SD)	58.7	(10.9)	59.6	(8.8)	0.73
Male sex, n (%)	25	(83.3)	28	(93.3)	0.21
ECOG performance status, n (%)					0.60
0	14	(46.7)	12	(40.0)	
1–2	16	(53.3)	18	(60.0)	
BMI in kg/m^2, mean (SD)	18.7	(3.0)	19.9	(2.9)	0.12
Anatomical site of tumor origin, n (%)					0.53
Oropharynx	13	(43.3)	8	(26.7)	
Hypopharynx	7	(23.3)	7	(23.3)	
Oral cavity	5	(16.7)	8	(26.7)	
Other	5	(16.7)	7	(23.3)	
Indication of PEG, n (%)					0.10
Chemoradiation for advanced disease	15	(50.0)	21	(70.0)	
Preoperative care	9	(30.0)	8	(26.7)	
Postoperative fistula	6	(20.0)	1	(3.3)	
Active cancer, n (%)	24	(80.0)	29	(96.7)	0.10
Inpatient setting, n (%)	24	(80.0)	26	(86.7)	0.49

BMI, body mass index; ECOG, Eastern Cooperative Oncology Group; PEG, percutaneous endoscopic gastrostomy; SD, standard deviation.

Table 2. Endoscopic findings, complications, and duration of PEG procedure

	Latex ($n = 30$)		Silicone ($n = 30$)		P
Endoscopic findings, n (%)					
Esophagitis	2	(6.7)	3	(10.0)	
Peptic gastric ulcer	3	(10.0)	3	(10.0)	
Duodenitis	2	(6.7)	2	(6.7)	
Peptic duodenal ulcer	4	(13.3)	1	(3.3)	
Total	11	(36.7)	9	(30.0)	0.58
Complications, n (%)					
Bleeding	1	(3.3)	3	(10.0)	
Respiratory failure	0	(0.0)	1	(3.3)	
Total	1	(3.3)	4	(13.3)	0.35
Procedure duration in minutes, mean (SD)	6.8	(1.0)	6.6	(1.3)	0.51

PEG, percutaneous endoscopic gastrostomy; SD, standard deviation.

Table 3. Primary and secondary outcomes

	Latex ($n = 30$)		Silicone ($n = 30$)		P
Primary outcome, mean (SD)					
Duration of PEG tubes in days	42.1	(31.4)	60.1	(36.4)	0.04
Secondary outcome, n (%)					
Mild infection	9	(30.0)	3	(10.0)	0.10
Granulated tissue formation	4	(13.0)	2	(7.0)	0.67
Leakage around the PEG tube	1	(3.3)	1	(3.3)	0.99

PEG, percutaneous endoscopic gastrostomy; SD, standard deviation.

significant. Only two cases of leakage around the PEG tube were found, which were evenly distributed across the two groups (Table 3).

DISCUSSION

This is the first study comparing the durability of silicone and latex PEG tubes. The duration of the silicone PEG tubes was significantly greater than that of the latex tubes. Such a difference was found in both of the analyzed parameters (i.e. longer mean duration and longer survival time). The mean duration of the tubes that were removed because of a malfunction was also higher in the silicone group.

The two randomized studies that compared silicone PEG tubes with polyurethane PEG tubes did not reveal differences in durability.[11,14] However, two published studies[11,13]

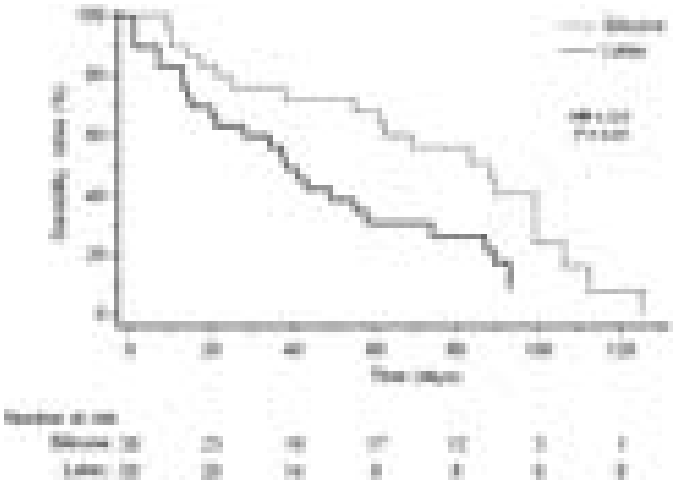


Fig. 1. Kaplan–Meier estimates of durability rates in each group. HR, hazard ratio.

found that silicone tubes are more susceptible to deterioration related to fungal colonization, a parameter that was not evaluated in the present study. Therefore, we are unable to conclude whether the lower durability of the latex PEG tubes was related to biological factors or to the physical characteristics of the latex. Further studies are needed to address this issue.

An advantage of the Introducer Technique is its low infection rate (1.4%; range, 0–3.6%).[8] The infection rate of the Pull Technique is approximately 8%.[18,19] These two techniques were compared by two prospective and randomized studies, which found a lower rate of infection with the Introducer Technique.[4,5]

The present study used 14 Fr silicone PEG tubes and 16 Fr latex PEG tubes. The median duration was 88 days for the silicone tubes and 38 days for the latex tubes. Horiuchi *et al*. used a 24 Fr PEG replacement device and found greater durability (i.e. the median duration was not reached even after 180 days of follow up).[5] Further randomized studies are needed to clarify whether a larger caliber tube is associated with greater durability.

The cost of each latex PEG tube is approximately 20- to 30-fold less than the cost of each silicone PEG tube. An important limitation of the present study was that it did not evaluate cost-effectiveness, which takes into account the cost and durability differences between the two types of tubes. This economic analysis and an evaluation of the patient's satisfaction with the different types of tubes should be investigated in future studies.

Van Den Hazel *et al*.[14] and Blacka *et al*.[11] reported higher complication rates among patients who had silicone PEG tubes compared with polyurethane PEG tubes, a finding that was not reported by Sartori *et al*.[13] The present study evaluated peristomal infection rates, granulated tissue formation, and leakage. No differences were found between the two types of tubes in these parameters, indicating that both tubes can be used with equal safety levels, at least with short follow-up periods.

In conclusion, latex PEG tubes are less durable than silicone PEG tubes, but both have similar rates of peristomal infection, granulated tissue formation, and leakage.

REFERENCES

1. Gauderer MW, Ponsky JL, Izant RJ Jr. Gastrostomy without laparotomy: A percutaneous endoscopic technique. *J. Pediatr. Surg.* 1980; **15**: 872–5.
2. Hashiba K. [Technique for opening a gastrostomy under endoscopic control and manipulation]. *Rev. Paul. Med.* 1980; **95**: 37–8.
3. Gauderer MW. Percutaneous endoscopic gastrostomy and the evolution of contemporary long-term enteral access. *Clin. Nutr.* 2002; **21**: 103–10.
4. Maetani I, Tada T, Ukita T, Inoue H, Sakai Y, Yoshikawa M. PEG with introducer or pull method: A prospective randomized comparison. *Gastrointest. Endosc.* 2003; **57**: 837–41.
5. Horiuchi A, Nakayama Y, Tanaka N, Fujii H, Kajiyama M. Prospective randomized trial comparing the direct method using a 24 Fr bumper-button-type device with the pull method for percutaneous endoscopic gastrostomy. *Endoscopy* 2008; **40**: 722–6.
6. Cappell MS. Risk factors and risk reduction of malignant seeding of the percutaneous endoscopic gastrostomy track from pharyngoesophageal malignancy: A review of all 44 known reported cases. *Am. J. Gastroenterol.* 2007; **102**: 1307–11.
7. Shastri YM, Hoepffner N, Tessmer A, Ackermann H, Schroeder O, Stein J. New introducer PEG gastropexy does not require prophylactic antibiotics: Multicenter prospective randomized double-blind placebo-controlled study. *Gastrointest. Endosc.* 2008; **67**: 620–8.
8. Campoli PM, Cardoso DM, Turchi MD, Ejima FH, Mota OM. Assessment of safety and feasibility of a new technical variant of gastropexy for percutaneous endoscopic gastrostomy: An experience with 435 cases. *BMC Gastroenterol.* 2009; **9**: 48.
9. Cruz I, Mamel JJ, Brady PG, Cass-Garcia M. Incidence of abdominal wall metastasis complicating PEG tube placement in untreated head and neck cancer. *Gastrointest. Endosc.* 2005; **62**: 708–11. quiz 52, 53.
10. Tucker AT, Gourin CG, Ghegan MD, Porubsky ES, Martindale RG, Terris DJ. 'Push' versus 'pull' percutaneous endoscopic gastrostomy tube placement in patients with advanced head and neck cancer. *Laryngoscope* 2003; **113**: 1898–902.
11. Blacka J, Donoghue J, Sutherland M *et al*. Dwell time and functional failure in percutaneous endoscopic gastrostomy tubes: A prospective randomized-controlled comparison between silicon polymer and polyurethane percutaneous endoscopic gastrostomy tubes. *Aliment. Pharmacol. Ther.* 2004; **20**: 875–82.
12. Crosby J, Duerksen DR. A prospective study of tube- and feeding-related complications in patients receiving long-term home enteral nutrition. *JPEN J. Parenter. Enteral Nutr.* 2007; **31**: 274–7.
13. Sartori S, Trevisani L, Nielsen I, Tassinari D, Ceccotti P, Abbasciano V. Longevity of silicone and polyurethane catheters in long-term enteral feeding via percutaneous endoscopic gastrostomy. *Aliment. Pharmacol. Ther.* 2003; **17**: 853–6.
14. Van Den Hazel SJ, Mulder CJ, Den Hartog G, Thies JE, Westhof W. A randomized trial of polyurethane and silicone percutaneous endoscopic gastrostomy catheters. *Aliment. Pharmacol. Ther.* 2000; **14**: 1273–7.
15. Oken MM, Creech RH, Tormey DC *et al*. Toxicity and response criteria of the Eastern Cooperative Oncology Group. *Am. J. Clin. Oncol.* 1982; **5**: 649–55.
16. Akkersdijk WL, van Bergeijk JD, van Egmond T *et al*. Percutaneous endoscopic gastrostomy (PEG): Comparison of

push and pull methods and evaluation of antibiotic prophylaxis. *Endoscopy* 1995; **27**: 313–16.
17. Kaplan E, Meier P. Nonparametric estimation from incomplete observations. *J. Am. Stat. Assoc.* 1958; **53**: 457–81.
18. Jafri NS, Mahid SS, Minor KS, Idstein SR, Hornung CA, Galandiuk S. Meta-analysis: Antibiotic prophylaxis to prevent peristomal infection following percutaneous endoscopic gastrostomy. *Aliment. Pharmacol. Ther.* 2007; **25**: 647–56.
19. Lipp A, Lusardi G. Systemic antimicrobial prophylaxis for percutaneous endoscopic gastrostomy. *Cochrane Database Syst. Rev.* 2006; **4**: CD005571.

Meta-analysis: Effect of the Introducer Technique compared with the Pull Technique on peristomal infection rate in patients undergoing percutaneous endoscopic gastrostomy (PEG)

ABSTRACT

Background and study aims: Peristomal infection is a main complication of percutaneous endoscopic gastrostomy (PEG). The Pull Technique appears to be associated with higher infection rates than the Introducer Technique, although the published results are controversial. This meta-analysis was performed to determine which technique is associated with a higher risk of infection.

Methods: Published studies were identified by searching the MEDLINE, EMBASE, CENTRAL-Cochrane, and LILACS databases and reference lists of articles and proceedings of two meetings: Digestive Disease Week and United European Gastroenterology Week. Two independent investigators identified studies that evaluated peristomal infection in patients undergoing PEG. Comparative studies (randomized and nonrandomized studies) and observational studies published since 1980 were included and analyzed separately. The summary effects were estimated using the random-effects model or fixed-effect model according to whether heterogeneity existed. Publication bias was assessed by visual examination of funnel plots and the Egger regression test.

Results: A total of 651 articles were reviewed. Six comparative studies and 10 observational studies comprising a total of 2,336 patients met the inclusion criteria. The comparative studies were homogeneous and without publication bias. The risk of infection in this study group was significantly higher with the Pull Technique (OR = 13.0, 95% confidence interval = 4.6-36.8, $p < 0.001$). Similarly, observational studies have also reported higher infection rates with the Pull Technique.

Conclusion: The Pull Technique is associated with a significantly higher risk of infection compared with the Introducer Technique.

INTRODUCTION

Percutaneous endoscopic gastrostomy (PEG) is a well-established medical procedure and has replaced surgical gastrostomy. The Pull Technique, proposed by Gauderer et al,[1] is used by almost all of the centers that perform PEG. This technique is widely accepted because it is easy to perform and produces good results. The disadvantage of this technique is its high infection rate even with the use of prophylactic antibiotics.[2] The Introducer Technique is an alternative that is more difficult to perform, but the risk of infection appears to be lower than the Pull Technique.[3] This apparent difference between infection rates has been justified by the fact that the gastric tube can be contaminated by bacterial flora of the oral cavity during its placement in the Pull Technique, whereas with the Introducer Technique, the gastric tube is implanted aseptically by percutaneous puncture.

Nonrandomized[4,5] and randomized[6,7] trials have compared these two techniques. One of these studies found a lower overall risk of complications in the group undergoing the Introducer Technique, but no significant difference was seen in the infection rate.[5] Another three studies reported significantly reduced infection rates with the Introducer Technique.[4,6,7] All studies reported a small number of events with the Introducer Technique, which reduces the precision of comparative measures.

Because of these controversial results and given this imprecision, the objective of the present meta-analysis was to compile the available data to obtain a more precise estimation of the infection risk associated with the two PEG techniques.

METHODS

This meta-analysis was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[8]

SEARCH STRATEGY

We searched MEDLINE (1980 to June 2010), EMBASE (1980 to April 2010), the Cochrane Central Register of Controlled Trials (CENTRAL; published papers up to June 2010), and the Latin-American and Caribbean Center on Health Sciences Information (LILACS; published papers up to June 2010) database using the search terms "percutaneous endoscopic gastrostomy" OR "PEG tube*" OR "PEG feed*" AND "infection." Searches of abstracts presented at the Digestive Disease Week (DDW) and United European Gastroenterology Week (UEGW) meetings up to 2010 were also carried out. We also hand-searched the bibliographies of all relevant primary articles and reviews to identify any articles that may have been missed by the electronic searches.

ELIGIBILITY CRITERIA

We identified English-language articles on PEG that showed rates of peristomal infection. Articles that clearly described the PEG technique used were included. The analyzed techniques were the Pull Technique proposed by Gauderer et al[1] and the many variations of the Introducer Technique (e.g., progressive dilatation proposed by Russell et al,[9] the use of a metal trocar,[3,10] or the use of a radially expandable trocar[11,12]). Studies that used the technique proposed by Sacks-Vine[13] or transnasal access were excluded.[14] We also included articles that described the use of prophylactic antibiotics and reported infection rates separately for each technique. On the other hand, we excluded articles that only showed the scores of infection or that measured only the severe forms of infection. We included comparative studies (randomized or nonrandomized) in which the outcome was the infection rate and the intervention was the gastrostomy procedure (Pull Technique *vs*. Introducer Technique). Observational studies in which one of the outcomes was the infection rate and one of the two gastrostomy techniques was used were also included and analyzed. All retrospective cohorts and case series evaluated by chart review were excluded.

STUDY SELECTION AND DATA EXTRACTION

Two independent reviewers screened all identified titles and abstracts and, for articles considered potentially eligible, abstracted their full-text reports. Discrepancies were discussed and resolved by consensus. The reviewers also collected data on the study location, year of publication, study design, PEG technique used, the use of antibiotics, diagnostic criteria for infection, number of participants, peristomal infection rate, and risk of bias.

ASSESSMENT OF RISK OF BIAS

Two review authors independently evaluated the methodological quality of the comparative studies using the Cochrane Collaboration tool for assessing risk of bias,[15] which consists of critically assessing criteria for evaluating different aspects of bias. These aspects include sequence generation, allocation concealment, blinding of assessment, incomplete outcome data, selective outcome reporting, and other potential sources of bias. Each item was assessed as adequate (i.e., low risk of bias), inadequate (i.e., high risk of bias), or unclear (i.e., uncertain risk of bias). Studies that were determined to be adequate in all of the main domains were considered to have a low risk of bias. Studies that were determined to be inadequate in one or more of the key domains were considered to have a high risk of bias. Studies that were unclear in at least one domain were considered to have at least a medium risk of bias.[16]

STATISTICAL ANALYSIS

Effect measures from each comparative study were reported as the odds ratio (OR) and 95% confidence interval (CI). The pooled effect was then calculated. The infection rate in each observational study was also calculated, and a summary effect was then obtained for each of the two gastrostomy techniques. Heterogeneity was assessed by visual inspection of a forest plot, the Cochran χ^2 test (Q-test), and the I^2 statistic.[17] A random-effects model or fixed-effect model was used, depending on

the presence or absence of heterogeneity. If a random-effects model was chosen, then studies were weighted using the DerSimonian and Laird method.[18] For the fixed-effect model, weighting was performed using the inverse variance method. We performed sensitivity analysis to explore the effect of the quality of the comparative studies. In this analysis, we excluded nonrandomized studies to verify the existence of any substantial difference in the summary effect. We also assessed the extent of publication bias of comparative studies through visual inspection of funnel plot asymmetry[19] and used the weighted-linear regression approach proposed by Egger et al[20] to provide a quantitative evaluation of the likelihood of publication bias. Statistical analyses were performed using Comprehensive Meta Analysis software version 2.2 (Biostat, Englewood, NJ, USA).[21]

RESULTS

STUDY SELECTION

After removing duplicate articles, 651 were identified. We screened the titles and abstracts of these articles and identified 168 potentially eligible articles. Following the assessment of 168 full-text articles, 16 were considered for inclusion, six of which were comparative studies[4-7,11,22] and ten were observational studies[3,23-31] (Fig. 1).

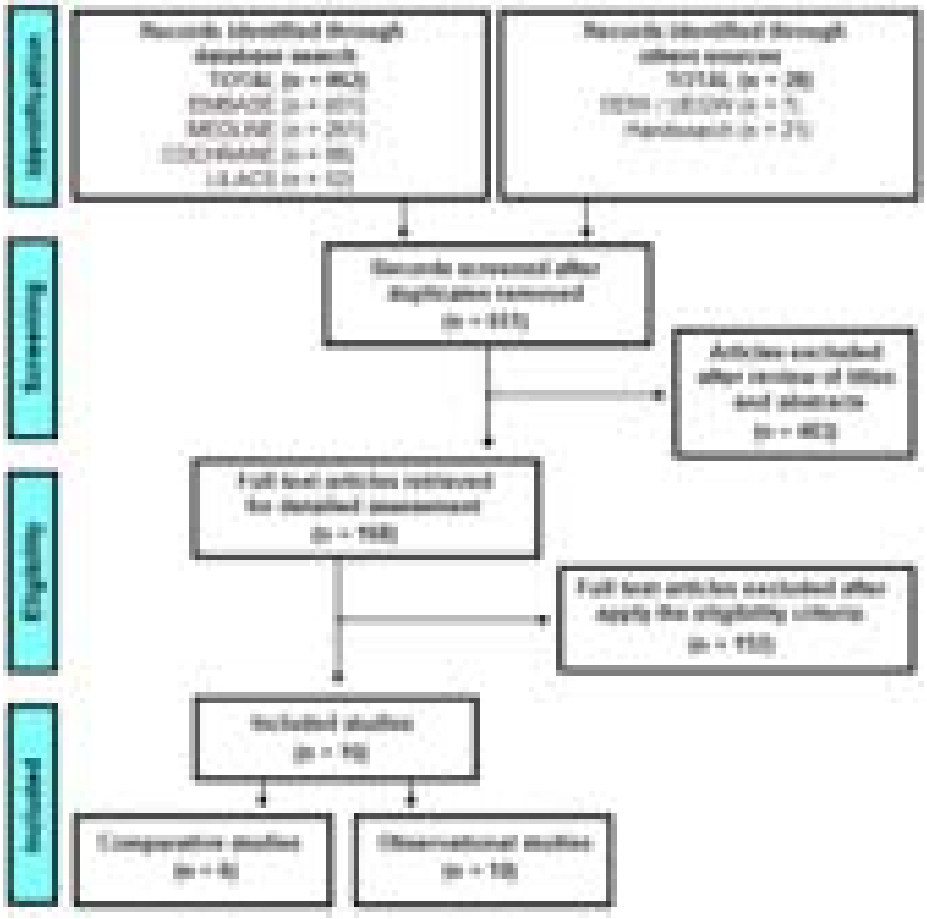


Fig. 1. Flowchart of study selection. DDW, Digestive Disease Week; UEGW, United European Gastroenterology Week.

COMPARATIVE STUDIES

Characteristics of included studies and risk of bias

In the six comparative studies, the intervention was gastrostomy (Pull Technique *vs*. Introducer Technique), and the outcome was the rate of peristomal infection in all of these studies. This group comprised a total of 564 patients, and antimicrobial prophylaxis was used in all patients. Two of these studies were randomized clinical trials,[6,7] and the other four were nonrandomized studies.[4,5,11,22] The risk of bias was classified as high in five studies[4,5,7,11,22] and medium in the other one[6] (Table 1). In all five studies classified as having high risk of bias the researchers who assessed outcomes were not blinded and the

outcome measurement could be influenced by lack of blinding. In the study classified as having medium risk of bias other potential threats to validity, such as differences in PEG tube diameter and the influence of short follow-up period were not ascertained.

Table 1. Baseline characteristics of comparative studies.

Study	City, country	Design	Intervention	Atb	Sample (n)	Infection (%)	Risk of bias
Deitel, 1988[22]	Toronto, Canada	Before-and-after	Pull Introducer	Yes Yes	28 28	21.4 0	high
Tucker, 2003[5]	Augusta, USA	Non randomized	Pull Introducer	Yes Yes	50 29	12.0 0	high
Toyama, 2007[11]	Chiba, Japan	Non randomized	Pull Introducer	Yes Yes	50 30	32.0 3.3	high
Hiki, 2008[4]	Tokyo, Japan	Before-and-after	Pull Introducer	Yes Yes	64 87	9.4 1.2	high
Maetani, 2003[6]	Tokyo, Japan	Randomized clinical trial	Pull Introducer	Yes Yes	29 29	31.0 0	medium
Horiuchi, 2008[7]	Komagane, Japan	Randomized clinical trial	Pull Introducer	Yes Yes	72 68	8.3 0	high

Atb, prophylactic antibiotics

Peristomal infection

The comparative studies were homogeneous. The *Q*-test for heterogeneity was not significant (p = 0.99), and the extent of the inconsistency between the results was zero (I^2 = 0%). Thus, we used the fixed-effect model and found that the Pull Technique was associated with a significantly increased risk of infection (OR = 13.0, 95% CI = 4.6-36.8, p < 0.0001) compared with the Introducer Technique (Fig. 2). We performed a sensitivity analysis by calculating only the results of randomized trials. The result was similar to the overall summary effect (Fig. 3).

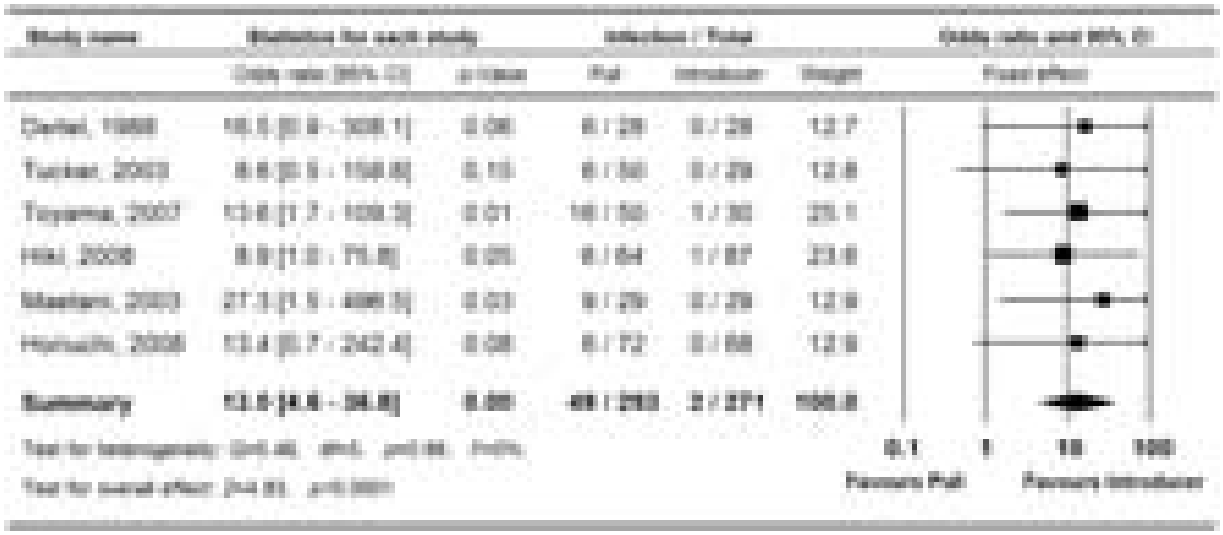


Fig. 2. Meta-analysis of comparative studies. Forest plot of the effect of the PEG technique on the risk of peristomal infection.

Fig. 3. Meta-analysis of comparative studies. Sensitivity analysis. Forest plot of the effect of the PEG technique on the risk of peristomal infection among randomized clinical trials.

Publication bias

Asymmetry was not observed upon visual inspection of the funnel plot (Fig.4). Additionally, a formal test was conducted using the method of Egger et al., which also indicated no publication bias (p = 0.22).

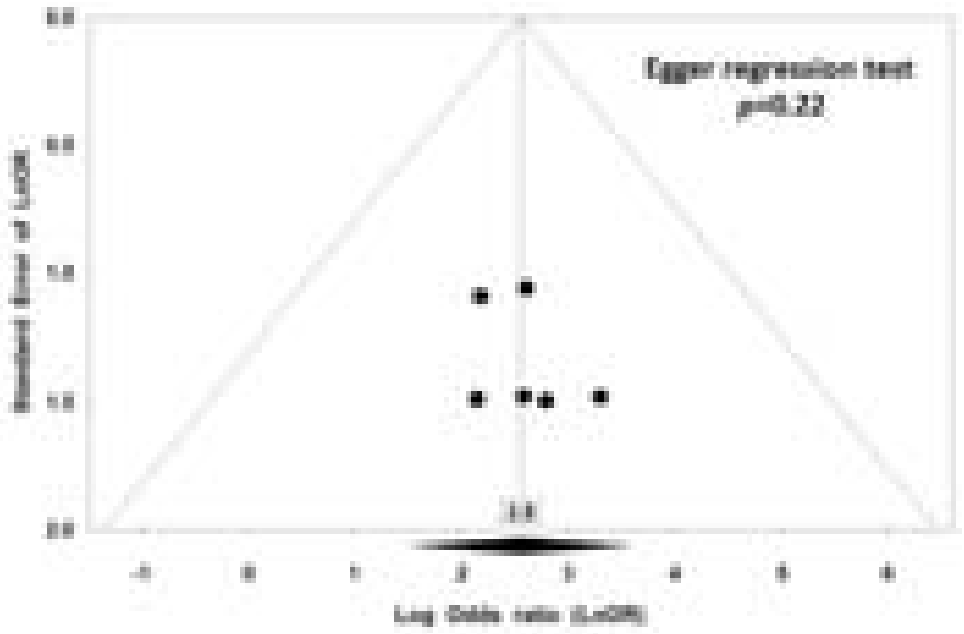


Fig. 4. Funnel plot of logarithm odds ratios (LnOR) *vs*. standard error for each comparative study.

OBSERVATIONAL STUDIES

Characteristics of included studies

The other group consisted of ten observational studies involving 1,772 patients, in which the outcome measured was peristomal infection. In seven of these studies was antimicrobial prophylaxis used. Among these ten studies, the Introducer Technique was performed in three, and the Pull Technique was performed in the remaining seven (Table 2).

Table 2. Baseline characteristics of observational studies.

Study	City, country	Study population	Technique	Atb	Sample (n)	Infection (%)
Robertson, 1996[23]	Boston, USA	All patients underwent PEG	Introducer	Yes	20	0
Dormann, 2006[24]	Munich, Germany	Unable to use the Pull Technique	Introducer	Yes	46	2.2
Campoli, 2009[3]	Goiania, Brazil	All patients underwent PEG	Introducer	No	435	0.2
Zopf, 2008[25]	Nuremberg, Germany	All patients underwent PEG	Pull	No	390	33.6
Mantsopoulos, 2010[26]	Erlangen, Germany	Head and neck cancer	Pull	No	101	21.8
Oh, 2007[27]	Seoul, Korea	All patients underwent PEG	Pull	Yes	31	12.9
Lee, 2007[28]	Taipei, Taiwan	All patients underwent PEG	Pull	Yes	302	6.9
Avery, 2008[29]	Leicester, United Kingdom	Head and neck cancer	Pull	Yes	219	6.8
de Souza e Mello, 2009[30]	Rio de Janeiro, Brazil	PEG in outpatients	Pull	Yes	136	6.6
Erdil, 2005[31]	Ankara, Turkey	All patients underwent PEG	Pull	Yes	92	3.3

Atb, prophylactic antibiotics

Peristomal infection

Heterogeneity was not evident among the studies that used the Introducer Technique (Q-statistic: $p = 0.21$, $I^2 = 36\%$). However, heterogeneity was found between the studies using the Pull Technique (Q-statistic: $p < 0.001$, $I^2 = 95\%$). For this latter reason, quantitative synthesis was obtained using the random-effects model (Fig. 5). The infection rate with the Pull Technique was 10.7% (95% CI = 4.9-21.8), which was higher than the 0.9% rate with the Introducer Technique (95% CI = 0.2-4.5].

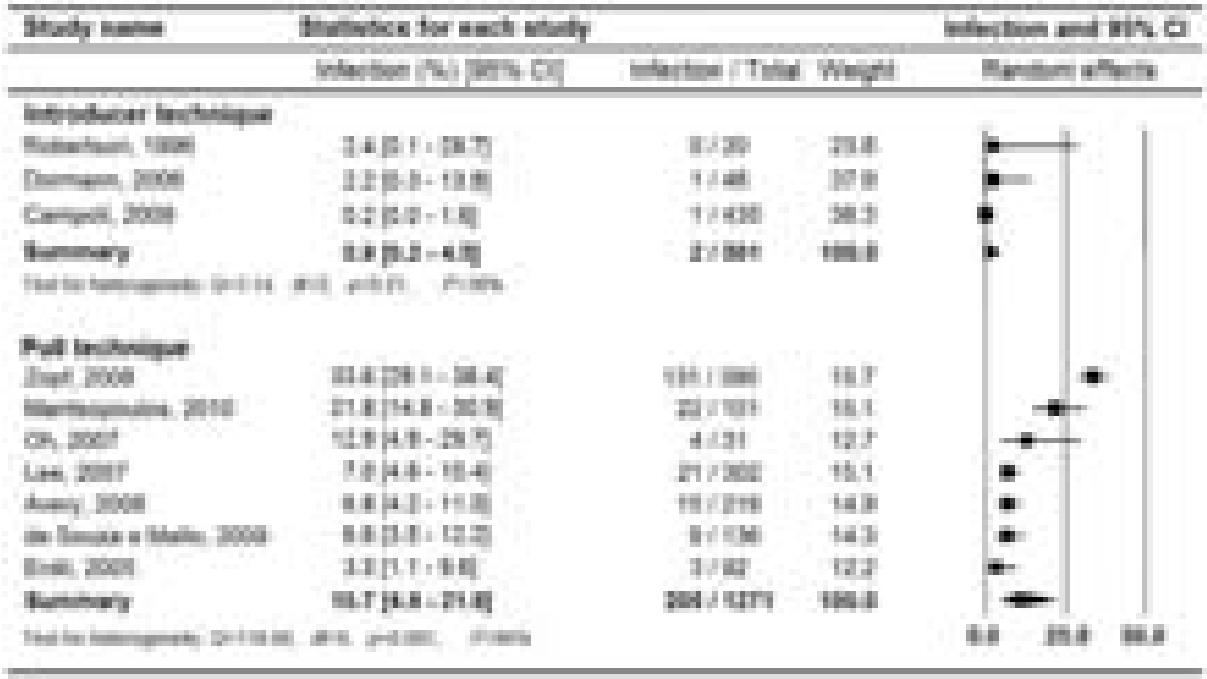


Fig. 5. Meta-analysis of observational studies. Forest plot of the effect of the PEG technique on infection rate.

DISCUSSION

This meta-analysis was performed to compare the peristomal infection rates associated with two PEG techniques: Pull Technique and Introducer Technique. Among the comparative studies, we found a significantly increased risk of infection with the Pull Technique (OR = 13.0, 95% CI = 4.6-36.8, $p < 0.0001$). The analysis of the observational studies also showed that the infection rates were higher when the Pull Technique was used. These results are biologically plausible, since the gastrostomy tube in the Pull Technique penetrates the stomach and abdominal walls after being contaminated by normal bacterial flora of the oral cavity, whereas with the Introducer Technique, the gastrostomy tube is inserted into the gastric cavity aseptically by percutaneous puncture.

Antimicrobial prophylaxis is well known to reduce the risk of peristomal infection in patients undergoing PEG.[2,32] The results presented here do not contain

confounding bias attributable to antibiotic use because the two PEG techniques applied antibiotics in all of the comparative studies of this meta-analysis.

Among the comparative studies, both randomized and nonrandomized studies were included, but the sensitivity analysis evaluated only randomized studies, demonstrating that the overall effect was robust and reliable. The absence of evidence of publication bias indicates that the search engine was sufficiently large and appropriate for considering studies with favorable and unfavorable results.

The preference for using the Pull Technique by the vast majority of PEG surgery centers worldwide may be attributable to the simplicity of performing this procedure, combined with the existence of a wide variety of commercially available kits devoted to this method. Several possibilities have been suggested to make the Introducer Technique easier. Gastropexy is a stage associated with considerable technical difficulty. An elegant way of affixing the stomach to the abdominal wall is the use of T-fasteners, which has been described by several authors.[5,33,34] T-fasteners are simple to place, but the metal hold needs to be removed by endoscopy several weeks after PEG. Recently, many authors have used a mechanical device that allows the easy application of sutures involving the abdominal wall and gastric wall.[7,10,11,24] Gastropexy performed with a long curved needle is another safe alternative.[3] The surgical stage at which the gastrostomy tube is inserted into the stomach has been performed using the progressive dilation technique,[5-7,9,34] a metal trocar,[3,10,24] or a radially expandable trocar.[11,12] These various tool options should be more easily available, which would make the Introducer Technique, a method associated with a low infection rate, more accessible.

We rated the methodological quality and risk of bias of the selected studies using the Cochrane Collaboration tool for assessing risk of bias. According to this tool only randomized blinded interventional trials could be classified as having low risk of bias. None of the six comparative studies included in this meta-analysis achieved a score of low risk of bias. Considering the great impact of infection rate on PEG, the scarcity of randomized trials examining this issue with adequate methodology is surprising. However, for some surgical or endoscopic procedures, it is quite difficult to achieve blinded observers due to perceptible differences in equipment or

procedure being tested. For instance, PEG tube material, tube size or gastropexy technique may have visible differences and the outcome measurement, such as peristomal infection, may be influenced by lack of blinding. Nevertheless, our meta-analysis reflects the current best evidence available on the peristomal infection risk comparing two PEG techniques. The implication for future research is that new randomized clinical trials with higher methodological quality should be conducted.

The findings of the present meta-analysis showed that the Introducer Technique is associated with lower infection rates and should be chosen as the first option when performing PEG.

References

1. Gauderer MW, Ponsky JL, Izant RJ, Jr. Gastrostomy without laparotomy: a percutaneous endoscopic technique. J Pediatr Surg 1980;15:872-875

2. Jafri NS, Mahid SS, Minor KS, et al. Meta-analysis: antibiotic prophylaxis to prevent peristomal infection following percutaneous endoscopic gastrostomy. Aliment Pharmacol Ther 2007;25:647-656

3. Campoli PM, Cardoso DM, Turchi MD, Ejima FH, Mota OM. Assessment of safety and feasibility of a new technical variant of gastropexy for percutaneous endoscopic gastrostomy: an experience with 435 cases. BMC Gastroenterol 2009;9:48

4. Hiki N, Maetani I, Suzuki Y, et al. Reduced risk of peristomal infection of direct percutaneous endoscopic gastrostomy in cancer patients: comparison with the pull percutaneous endoscopic gastrostomy procedure. J Am Coll Surg 2008;207:737-744

5. Tucker AT, Gourin CG, Ghegan MD, et al. 'Push' versus 'pull' percutaneous endoscopic gastrostomy tube placement in patients with advanced head and neck cancer. Laryngoscope 2003;113:1898-1902

6. Maetani I, Tada T, Ukita T, et al. PEG with introducer or pull method: a prospective randomized comparison. Gastrointest Endosc 2003;57:837-841

7. Horiuchi A, Nakayama Y, Tanaka N, Fujii H, Kajiyama M. Prospective randomized trial comparing the direct method using a 24 Fr bumper-button-type device with the pull method for percutaneous endoscopic gastrostomy. Endoscopy 2008;40:722-726

8. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. Ann Intern Med 2009;151:264-269, W264

9. Russell TR, Brotman M, Norris F. Percutaneous gastrostomy. A new simplified and cost-effective technique. Am J Surg 1984;148:132-137

10. Shastri YM, Hoepffner N, Tessmer A, et al. New introducer PEG gastropexy does not require prophylactic antibiotics: multicenter prospective randomized double-blind placebo-controlled study. Gastrointest Endosc 2008;67:620-628

11. Toyama Y, Usuba T, Son K, et al. Successful new method of extracorporeal percutaneous endoscopic gastrostomy (E-PEG). Surg Endosc 2007;21:2034-2038

12. Sabnis A, Liu R, Chand B, Ponsky J. SLiC technique. A novel approach to percutaneous gastrostomy. Surg Endosc 2006;20:256-262

13. Sacks BA, Vine HS, Palestrant AM, et al. A nonoperative technique for establishment of a gastrostomy in the dog. Invest Radiol 1983;18:485-487

14. Dumortier J, Lapalus MG, Pereira A, et al. Unsedated transnasal PEG placement. Gastrointest Endosc 2004;59:54-57

15. Higgins JP, Altman DG. Assessing risk of bias in included studies. In: Higgins JP, Green S eds, Cochrane Handbook for Systematic Reviews of Interventions. Chichester, UK: John Wiley & Sons; 2008:187-206

16. Boehm K, Borrelli F, Ernst E, et al. Green tea (Camellia sinensis) for the prevention of cancer. Cochrane Database Syst Rev 2009:CD005004

17. Higgins JP, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. BMJ 2003;327:557-560

18. DerSimonian R, Laird N. Meta-analysis in clinical trials. Control Clin Trials 1986;7:177-188

19. Light RJ, Pillemer DB. Summing up: The science of reviewing research. Cambridge, MA: Harvard University Press; 1984

20. Egger M, Davey Smith G, Schneider M, Minder C. Bias in meta-analysis detected by a simple, graphical test. BMJ 1997;315:629-634

21. Borenstein M, Hedges LV, Higgins JPT, Rothstein HR. Comprehensive Meta Analysis. Version 2.2. In. Englewood, NJ: Biostat; 2009

22. Deitel M, Bendago M, Spratt EH, Burul CJ, To TB. Percutaneous endoscopic gastrostomy by the "pull" and "introducer" methods. Can J Surg 1988;31:102-104

23. Robertson FM, Crombleholme TM, Latchaw LA, Jacir NN. Modification of the "push" technique for percutaneous endoscopic gastrostomy in infants and children. J Am Coll Surg 1996;182:215-218

24. Dormann AJ, Wejda B, Kahl S, et al. Long-term results with a new introducer method with gastropexy for percutaneous endoscopic gastrostomy. Am J Gastroenterol 2006;101:1229-1234

25. Zopf Y, Konturek P, Nuernberger A, et al. Local infection after placement of percutaneous endoscopic gastrostomy tubes: a prospective study evaluating risk factors. Can J Gastroenterol 2008;22:987-991

26. Mantsopoulos K, Zenk J, Konturek PC, Iro H. Local infection after percutaneous endoscopic gastrostomy in ENT tumor patients: evaluation of the influence of the abdominal thickness and other parameters. Med Sci Monit 2010;16:CR116-123

27. Oh HJ, Shim KN, Choi HJ, et al. Contribution of Nasal Methicillin-Resistant Staphylococcus Aureus Colonization to Percutaneous Endoscopic Gastrostomy Infection. Gastrointest Endosc 2007;65:AB188

28. Lee TH, Shih LN, Lin JT. Clinical experience of percutaneous endoscopic gastrostomy in Taiwanese patients--310 cases in 8 years. J Formos Med Assoc 2007;106:685-689

29. Avery C, Shenoy S, Shetty S, et al. The prospective experience of a maxillofacial surgeon with the percutaneous endoscopic gastrostomy technique. Int J Oral Maxillofac Surg 2008;37:140-148

30. de Souza e Mello GF, Lukashok HP, Meine GC, et al. Outpatient percutaneous endoscopic gastrostomy in selected head and neck cancer patients. Surg Endosc 2009;23:1487-1493

31. Erdil A, Saka M, Ates Y, et al. Enteral nutrition via percutaneous endoscopic gastrostomy and nutritional status of patients: five-year prospective study. J Gastroenterol Hepatol 2005;20:1002-1007

32. Lipp A, Lusardi G. Systemic antimicrobial prophylaxis for percutaneous endoscopic gastrostomy. Cochrane Database Syst Rev 2006:CD005571

33. Akkersdijk WL, van Bergeijk JD, van Egmond T, et al. Percutaneous endoscopic gastrostomy (PEG): comparison of push and pull methods and evaluation of antibiotic prophylaxis. Endoscopy 1995;27:313-316

34. Foster JM, Filocamo P, Nava H, et al. The introducer technique is the optimal method for placing percutaneous endoscopic gastrostomy tubes in head and neck cancer patients. Surg Endosc 2007;21:897-901

7. DISCUSSÃO

Uma nova variante técnica de gastropexia com agulha longa e curva foi descrita e demonstrada sua segurança e exequibilidade. O índice de infecção encontrado com esta nova variante técnica de gastropexia foi considerado baixo e um segundo estudo revelou ser ainda menor que o índice de infecção observado quando a gastropexia era realizada pela técnica que utiliza duas agulhas retas. Foi realizado um ensaio clínico randomizado comparando tubos de látex com tubos de silicone e foi observada maior durabilidade entre os tubos de silicone. Por fim, os resultados da metanálise nos mostram que os índices de infecção nas GEP realizadas pela Técnica de Tração são significativamente maiores quando comparados com a Técnica de Punção.

GASTROPEXIA COM AGULHA LONGA E CURVA

A gastropexia se reveste de grande importância, pois oferece segurança em relação ao risco de desabamento do estômago se o tubo de gastrostomia for inadvertidamente removido nos primeiros dias de pós-operatório. É também possível que ela reduza os riscos de vazamento de secreção gástrica para a cavidade peritoneal (Tucker et al. 2003) .

A proposta de realizar a gastropexia da forma como foi descrita, com agulha longa e curva (Campoli et al. 2009), surgiu da necessidade de tornar mais fácil, simples e rápida esta etapa do procedimento, considerada até então de difícil execução. Uma alternativa interessante seria o uso do dispositivo mecânico para realizar esta sutura apresentada por Dormann *et al* (2000a) e reproduzida por vários outros autores (Saito et al. 2007, Toyama et al. 2007, Horiuchi et al. 2008, Shastri et al. 2008), inclusive no Brasil (Giordano-Nappi et al. 2007). Acreditamos que a agulha longa e curva por nós utilizada é de mais

fácil acesso pois faz parte do material de sutura regularmente disponível nos hospitais.

A exemplo de outros autores (Akkersdijk et al. 1995, Toyama et al. 2007, Horiuchi et al. 2008), o índice de infecção com esta variante técnica, no presente estudo, foi avaliado apenas por critérios clínicos o que envolve certa subjetividade desta aferição. Em 1987 Jain *et al* (1987) descreveram critérios objetivos que permitem quantificar a presença de infecção em graus variáveis. Esta proposta de classificação é utilizada por diversos autores (Hiki et al. 2008, Shastri et al. 2008) e os novos estudos a serem conduzidos devem utilizar este recurso para obter dados mais robustos.

Acreditamos que seja muito pertinente a realização de um estudo de custo-efetividade tomando por base o procedimento padrão de GEP pela Técnica de Tração comparando com a forma de realizar GEP aqui descrita. A hipótese a ser testada é que a relação custo-efetividade seria favorável ao procedimento aqui proposto.

Existem alguns problemas e dificuldades na execução da gastropexia com a agulha longa e curva. Por ser grande a área de trabalho usada ao realizar a gastropexia, é possível que o risco de lesão de outras vísceras seja maior do que quando a GEP é feita sem gastropexia. É descrito como sendo de fundamental importância manter o estômago bastante insuflado ao aplicar a sutura, pois isto mantém as vísceras vizinhas afastadas reduzindo o risco de iatrogenia (Schrag et al. 2007). Outro problema se refere à espessura da parede abdominal. Pacientes obesos ou mesmo aqueles com musculatura abdominal muito desenvolvida, oferecem dificuldade na aplicação do ponto de sutura. Nesta circunstância a gastropexia com agulha longa e curva deve ser substituída pela gastropexia com duas agulhas retas. Outra alternativa em pacientes obesos é a utilização da Técnica de Tração (McGarr & Kirby 2007).

AGULHA LONGA E CURVA COMPARADA COM DUAS AGULHAS RETAS

Apesar de todas as limitações de um estudo que compara os dados atuais com dados históricos, o estudo observacional e analítico aqui apresentado

levanta a possibilidade de que o índice de infecção seja significativamente menor ao realizar a gastropexia com a agulha longa e curva, em relação à gastropexia com duas agulhas retas. É um resultado com plausibilidade biológica, pois na gastropexia com duas agulhas retas há contato da alça de polipectomia contaminada com o fio de sutura, o que não ocorre com a nova variante técnica de gastropexia aqui descrita.

No grupo em que a gastropexia foi realizada com duas agulhas retas houve maior percentual de pacientes que apresentaram insuficiência respiratória. Este achado não deve ser atribuído à técnica e sim à etapa inicial da curva de aprendizado, na qual os pacientes no limiar de necessitarem de traqueostomia foram submetidos à GEP, gerando este elevado índice de insuficiência respiratória. Estes pacientes precisam ser identificados e encaminhados para realizar traqueostomia antes de realizar a GEP. Outros autores relatam experiência muito parecida (Gibson et al. 1992, Riley & Strauss 1992). Oakley *et al* (2009) propõem que é necessário um protocolo formal de avaliação dos pacientes portadores de tumores de cabeça e pescoço para reduzir este risco.

Neste estudo existem algumas diferenças entre os dois grupos, que não puderam ser controladas em razão da natureza comparativa com um grupo histórico. No grupo em que a gastropexia foi realizada com a agulha longa e curva, havia maior proporção de pacientes portadores de tumores de cabeça e pescoço. Este fato é explicado pela demanda crescente por GEP empreendida pelo Setor de Cabeça e Pescoço do Hospital Araújo Jorge, especialmente nos últimos anos. Esta demanda crescente é explicada pela observação de que os pacientes portadores de tumores de cabeça e pescoço submetidos à GEP toleram melhor o tratamento instituído, seja cirúrgico, quimioterápico ou radioterápico (Morton et al. 2009). Outra importante diferença entre os dois grupos estudados está no fato de que foram excluídos pacientes obesos no grupo submetido à gastropexia com a agulha longa e curva. É possível que a influência deste detalhe tenha sido muito baixa, pois apenas três pacientes foram excluídos por este motivo dentro de um universo de 515 pacientes (Campoli et al. 2009).

COMPARAÇÃO DO TUBO DE LÁTEX COM O TUBO DE SILICONE

O custo do tubo de látex é aproximadamente 30 vezes menor que o custo do tubo de silicone ou de poliuretano. Este é o principal motivo do uso preferencial do primeiro tubo na nossa instituição. Por ser desenhada para uso como sonda vesical, é precário o seu sistema de conexão com os equipos usados para administrar dieta, o que não chega a inviabilizar o seu uso. Apesar desta desvantagem, o tubo de látex é adequado ao perfil de pacientes com neoplasias malignas, nos quais o tempo de uso da gastrostomia geralmente é muito menor se comparada com pacientes cuja indicação é neurológica ou outras doenças crônicas com maior expectativa de sobrevivência.

Existem estudos que comparam tubos de silicone com tubos de poliuretano, no entanto não existem estudos comparativos com os tubos de látex. Os estudos que compararam silicone com poliuretano não encontraram diferença de durabilidade e alguns referem uma maior frequência de complicações associadas ao uso de tubos de silicone (Van Den Hazel et al. 2000, Sartori et al. 2003, Blacka et al. 2004).

O ensaio clínico randomizado aqui apresentado é o primeiro que compara tubos de látex com tubos de silicone. Neste estudo a durabilidade dos tubos de látex foi significativamente inferior à durabilidade dos tubos de silicone. Não foram observadas diferenças quanto ao risco de infecção cirúrgica, formação de tecido de granulação ou vazamento ao redor do tubo (Campoli et al. 2010). Estes achados reforçam a idéia de que os tubos de látex, mesmo com menor durabilidade, são adequados para o nosso perfil de pacientes que fazem uso de gastrostomia por curtos períodos de tempo.

INFECÇÃO EM DUAS TÉCNICAS DE GEP - METANÁLISE

Esta metanálise é a primeira que compara os índices de infecção periostomal entre as duas mais importantes técnicas de execução de gastrostomia. A Técnica de Tração, ostensivamente utilizada no mundo todo, está associada a índices de infecção 13 vezes maior quando comparada à Técnica de Punção, praticada em poucos centros ao redor do mundo. É um resultado

surpreendente que deve ser levado em consideração por ocasião da escolha do método a ser usado para realizar gastrostomia.

A homogeneidade e ausência de viés de seleção entre os estudos comparativos contribuem para tornar robustos os resultados encontrados. A limitação desta metanálise se refere ao fato de ter usado estudos comparativos randomizados e não-randomizados, sendo a quase totalidade deles com elevado risco de viés. Esta opção foi adotada devido à escassez de ensaios randomizados acerca deste tema. Esta limitação passa a ser menos importante quando a análise de sensibilidade revelou que os resultados da metanálise apenas com os ensaios randomizados apontam na mesma direção dos resultados com todos os estudos comparativos.

Também foi feita uma metanálise de estudos observacionais cujo resultado também reforça a idéia de que os índices de infecção com a Técnica de Tração são maiores se comparados com a Técnica de Punção.

VALIDAÇÃO DE PROCEDIMENTO CIRÚRGICO

O processo de validação de um novo tratamento cirúrgico deveria seguir os mesmos passos do processo de validação de novos medicamentos. Após a comprovação da eficácia (fase II), o novo tratamento (cirúrgico ou medicamentoso) deve ser confrontado com o tratamento padrão, na forma de ensaio clínico randomizado (fase III). Em outras palavras, um novo tratamento, mesmo sendo eficaz, nem sempre é mais benéfico que o tratamento padronizado. Ao conduzir um estudo randomizado, o viés de seleção teoricamente é anulado pelo processo de randomização e os fatores de confundimento, conhecidos ou não, são uniformemente distribuídos entre os braços estudados (Kassell & Dumont 2006). A quantidade de ensaios clínicos randomizados aumenta a cada ano e os seus resultados fornecem a mais sólida evidência acerca de qual é o melhor tratamento a ser administrado a cada paciente (Tiruvoipati et al. 2006).

Na prática, a maioria das evidências disponíveis acerca dos tratamentos cirúrgicos é proveniente de estudos observacionais, sendo poucas as evidências originadas de ensaios clínicos randomizados (Anyanwu & Treasure 2004). A

grande crítica a esta situação é que os estudos observacionais, não controlados, muitas vezes têm viés de seleção e seus resultados podem não ser aplicáveis à população geral (McKee et al. 1999).

São muitas as dificuldades enfrentadas para realizar ensaios clínicos randomizados em cirurgia. A comparação do novo procedimento cirúrgico com placebo ou com o não-tratamento geralmente é inadequada ou antiética. Estudos cegos na maioria das vezes não são praticáveis, pois o cirurgião e seus auxiliares conhecem a operação que foi executada. A maioria dos novos procedimentos cirúrgicos é adequada a uma pequena parcela de pacientes, o que muitas vezes torna impossível recrutar uma quantidade suficiente de casos para atingir o tamanho previsto da amostra (Sade 2006). Em cirurgia, é muito difícil fazer com que a alocação seja sigilosa (*allocation concealment*) pois geralmente tanto o pesquisador quanto o paciente sabem com antecedência qual procedimento será realizado (Anyanwu & Treasure 2004).

Os resultados de um novo procedimento cirúrgico têm direta relação com a curva de aprendizado o que torna as medidas dos desfechos progressivamente melhores a cada novo paciente alocado no estudo. Este fenômeno não é observado em ensaios clínicos que testam novas drogas (Sade 2006). Os procedimentos cirúrgicos têm estreita dependência com a habilidade do cirurgião e muitas vezes são executados por pequenos grupos altamente selecionados e fortemente determinados a obter sucesso com a técnica utilizada (Piantadosi 2005). Este fator gera baixa validade externa dos resultados encontrados.

Além disso, o cirurgião é ensinado a ter atitudes e convicções que o leva a acreditar que é desnecessário realizar estudos experimentais. Os seguintes itens reforçam esta idéia: o respeito pela opinião e pela experiência do cirurgião; o conceito antecipado de que o tratamento cirúrgico está associado a um grande e benéfico efeito terapêutico; a confiança de que haverá ganhos com o procedimento cirúrgico; a dificuldade ou o conceito de que não é necessário realizar um estudo randomizado; o não reconhecimento da existência de viés de seleção e viés do observador; a confiança de que a relação risco/benefício será

favorável e por fim a escolha de pacientes cuidadosamente selecionados (Piantadosi 2006).

Existem opiniões contrárias em relação a este conceito de que são necessários estudos randomizados para validar técnicas cirúrgicas. Kassell e Dumont argumentam que "o progresso da cirurgia pode ser observado ao longo de milhares de anos sendo que os procedimentos efetivos são adotados enquanto os procedimentos não efetivos são descartados, sem a necessidade dos ensaios clínicos". Do ponto de vista pragmático, segundo estes autores, muitos procedimentos cirúrgicos não são passíveis de serem estudados por meio de ensaios clínicos por causa do pequeno número de casos o que exigiria um tempo de alocação exageradamente longo. Além disso, tem sido demonstrado que em muitos ensaios randomizados com resultados negativos, não há suficiente poder estatístico para aceitar ou recusar a hipótese nula, decorrente do pequeno número de casos (Kassell & Dumont 2006).

8. CONCLUSÕES E RECOMENDAÇÕES

A gastropexia com agulha longa e curva é exequível e segura. A gastropexia com esta agulha esteve associada a baixos índices de infecção do sítio cirúrgico, sugerindo que essa variante técnica possa substituir, com vantagens, a gastropexia com duas agulhas retas. Os tubos de látex, ainda que menos duráveis, parecem ser adequados para uso em GEP. Estudos randomizados deverão ser conduzidos para esclarecer se a GEP pela Técnica de Tração deve dar lugar à GEP pela Técnica de Punção.

O processo de validação de um procedimento cirúrgico é difícil e complexo. Mesmo assim, é imperativo que novos ensaios clínicos randomizados e com número adequado de participantes sejam conduzidos para confirmar a eficácia desta proposta de mudança do padrão de execução de GEP.

Avaliações econômicas com estudos de custo-efetividade também precisam ser realizadas para testar a hipótese de melhor viabilidade econômica desta nova tecnologia proposta.

9. REFERÊNCIAS

Ahmad I, Mouncher A, Abdoolah A, Stenson R, Wright J, Daniels A, Tillett J, Hawthorne AB, Thomas G 2003. Antibiotic prophylaxis for percutaneous endoscopic gastrostomy--a prospective, randomised, double-blind trial. *Aliment Pharmacol Ther 18*: 209-215.

Akkersdijk WL, van Bergeijk JD, van Egmond T, Mulder CJ, van Berge Henegouwen GP, van der Werken C, van Erpecum KJ 1995. Percutaneous endoscopic gastrostomy (PEG): comparison of push and pull methods and evaluation of antibiotic prophylaxis. *Endoscopy 27:* 313-316.

Anagnostopoulos GK, Kostopoulos P, Arvanitidis DM 2003. Buried bumper syndrome with a fatal outcome, presenting early as gastrointestinal bleeding after percutaneous endoscopic gastrostomy placement. *J Postgrad Med 49:* 325-327.

Anyanwu AC, Treasure T 2004. Surgical research revisited: clinical trials in the cardiothoracic surgical literature. *Eur J Cardiothorac Surg 25:* 299-303.

Blacka J, Donoghue J, Sutherland M, Martincich I, Mitten-Lewis S, Morris P, Meredith G 2004. Dwell time and functional failure in percutaneous endoscopic gastrostomy tubes: a prospective randomized-controlled comparison between silicon polymer and polyurethane percutaneous endoscopic gastrostomy tubes. *Aliment Pharmacol Ther 20:* 875-882.

Brown AS, Mueller PR, Ferrucci JT, Jr 1986. Controlled percutaneous gastrostomy: nylon T-fastener for fixation of the anterior gastric wall. *Radiology 158:* 543-545.

Campoli PMO, Ejima FH, Cardoso DMM, BarrosJr AP, SouzaFo PP, Freitas MAF, Castro FCF, Barreto PAQ, Mota OM 2007a. Gastrostomia endoscópica percutânea executada pela técnica de sutura e punção percutânea. *GED Gastroenterologia Endoscopia Digestiva 26:* 109-113.

Campoli PMO, Ejima FH, Cardoso DMM, Barreto PAQ, Pires RdD, Meneghini AJ, Curado MP, Oliveira JCd, Mota OM 2007b. Percutaneous endoscopic gastrostomy in advanced head and neck cancer. *ABCD Arq Bras Cir Dig 20:* 97-101.

Campoli PM, Cardoso DM, Turchi MD, Ejima FH, Mota OM 2009. Assessment of safety and feasibility of a new technical variant of gastropexy for percutaneous endoscopic gastrostomy: an experience with 435 cases. *BMC Gastroenterol 9:* 48.

Campoli PM, Cardoso DM, Turchi MD, Mota OM 2010. Clinical trial: a randomized study comparing the durability of silicone and latex percutaneous endoscopic gastrostomy (PEG) tubes. *Dig Endosc:* in press. Published online: 7 DEC 2010 (http://onlinelibrary.wiley.com/doi/10.1111/j.1443-1661.2010.01051.x/abstract).

Cappell MS 2007. Risk factors and risk reduction of malignant seeding of the percutaneous endoscopic gastrostomy track from pharyngoesophageal malignancy: a review of all 44 known reported cases. *Am J Gastroenterol 102:* 1307-1311.

Cooper JD, Clayman RV, Krummel TM, Schauer PR, Thompson C, Moreno JD 2008. Inside the operating room--balancing the risks and benefits of new surgical procedures: a collection of perspectives and panel discussion. *Cleve Clin J Med 75 Suppl 6:* S37-48.

Crombleholme TM, Jacir NN 1993. Simplified "push" technique for percutaneous endoscopic gastrostomy in children. *J Pediatr Surg 28:* 1393-1395.

Cruz I, Mamel JJ, Brady PG, Cass-Garcia M 2005. Incidence of abdominal wall metastasis complicating PEG tube placement in untreated head and neck cancer. *Gastrointest Endosc 62:* 708-711.

Deitel M, Bendago M, Spratt EH, Burul CJ, To TB 1988. Percutaneous endoscopic gastrostomy by the "pull" and "introducer" methods. *Can J Surg 31:* 102-104.

Dewald CL, Hiette PO, Sewall LE, Fredenberg PG, Palestrant AM 1999. Percutaneous gastrostomy and gastrojejunostomy with gastropexy: experience in 701 procedures. *Radiology 211:* 651-656.

Dormann AJ, Glosemeyer R, Leistner U, Deppe H, Roggel R, Wigginghaus B, Huchzermeyer H 2000a. Modified percutaneous endoscopic gastrostomy (PEG) with gastropexy--early experience with a new introducer technique. *Z Gastroenterol 38:* 933-938.

Dormann AJ, Wigginghaus B, Risius H, Kleimann F, Kloppenborg A, Rosemann J, Padel Y, Pohl R, Baum HH, Lubbesmeier A, Schwab J, Kuhlkamp V, Gutjahr W, Lindenburger W, Schutz H, Huchzermeyer H 2000b. Antibiotic prophylaxis in percutaneous endoscopic gastrostomy (PEG)--results from a prospective randomized multicenter trial. *Z Gastroenterol 38:* 229-234.

Dormann AJ, Wejda B, Kahl S, Huchzermeyer H, Ebert MP, Malfertheiner P 2006. Long-term results with a new introducer method with gastropexy for percutaneous endoscopic gastrostomy. *Am J Gastroenterol 101:* 1229-1234.

Figueiredo FA, da Costa MC, Pelosi AD, Martins RN, Machado L, Francioni E 2007. Predicting outcomes and complications of percutaneous endoscopic gastrostomy. *Endoscopy 39:* 333-338.

Foster JM, Filocamo P, Nava H, Schiff M, Hicks W, Rigual N, Smith J, Loree T, Gibbs JF 2007. The introducer technique is the optimal method for placing percutaneous endoscopic gastrostomy tubes in head and neck cancer patients. *Surg Endosc 21:* 897-901.

Friedmann R, Feldman H, Sonnenblick M 2007. Misplacement of percutaneously inserted gastrostomy tube into the colon: report of 6 cases and review of the literature. *JPEN J Parenter Enteral Nutr 31:* 469-476.

Fyock CJ, Kethu SR 2009. PEG placement causing liver perforation. *J Clin Gastroenterol 43:* 385.

Gauderer MW, Ponsky JL, Izant RJ, Jr 1980. Gastrostomy without laparotomy: a percutaneous endoscopic technique. *J Pediatr Surg 15:* 872-875.

Gauderer MW 2002. Percutaneous endoscopic gastrostomy and the evolution of contemporary long-term enteral access. *Clin Nutr 21:* 103-110.

Gibson SE, Wenig BL, Watkins JL 1992. Complications of percutaneous endoscopic gastrostomy in head and neck cancer patients. *Ann Otol Rhinol Laryngol 101:* 46-50.

Giordano-Nappi JH, Ishioka S, Maluf-Filho F, Hondo FY, Matuguma SE, Sakai P 2007. A new device for the introducer technique for percutaneous endoscopic gastrostomy placement. *Endoscopy 39:* E274.

Gomez NA, Alvarez Ludwig R, Mite A, Andrade JP, Alvarez JR, Vargas PE 2000. [Percutaneous endoscopic gastrotomy (GEP): designed reusable (NAGEP) for one time endoscopic technique. Experimental study in dogs]. *Acta Gastroenterol Latinoam 30:* 233-235.

Hashiba K, Fabbri CE, Cappellanes CA, Branco PD, Birolini D, Oliveira MR 1984. Endoscopic percutaneous gastrostomy without laparotomy. *Endoscopy 16:* 219-222.

Hashiba K 1980. [Technic for opening a gastrostomy under endoscopic control and manipulation]. *Rev Paul Med 95:* 37-38.

Hashiba K 1987. Endoscopic gastrostomy. *Endoscopy 19 Suppl 1:* 23-24.

Hiki N, Maetani I, Suzuki Y, Washizawa N, Fukuda T, Yamaguchi T 2008. Reduced risk of peristomal infection of direct percutaneous endoscopic gastrostomy in cancer patients: comparison with the pull percutaneous endoscopic gastrostomy procedure. *J Am Coll Surg 207:* 737-744.

Ho CS 1983. Percutaneous gastrostomy for jejunal feeding. *Radiology 149:* 595-596.

Horbach T, Teske V, Hohenberger W, Siassi M 2007. Endoscopic therapy of the buried bumper syndrome: a clinical algorithm. *Surg Endosc 21:* 1359-1362.

Horiuchi A, Nakayama Y, Tanaka N, Fujii H, Kajiyama M 2008. Prospective randomized trial comparing the direct method using a 24 Fr bumper-button-type device with the pull method for percutaneous endoscopic gastrostomy. *Endoscopy 40:* 722-726.

Jafri NS, Mahid SS, Minor KS, Idstein SR, Hornung CA, Galandiuk S 2007. Meta-analysis: antibiotic prophylaxis to prevent peristomal infection following percutaneous endoscopic gastrostomy. *Aliment Pharmacol Ther 25:* 647-656.

Jain NK, Larson DE, Schroeder KW, Burton DD, Cannon KP, Thompson RL, DiMagno EP 1987. Antibiotic prophylaxis for percutaneous endoscopic gastrostomy. A prospective, randomized, double-blind clinical trial. *Ann Intern Med 107:* 824- 828.

Jascalevich ME 1967. Experimental trocar gastrostomy. *Surgery 62:* 452-453.

Jones S 1875. Gastrostomy for stricture (?cancerous) of oesophagus: Death from bronchitis forty days after operation. *Lancet 1:* 678-679.

Kadota T, Nakagawa K, Taguchi J, Ono H, Hiraide H, Tamakuma S, Ueno F 1991. A simplified percutaneous endoscopic gastrostomy using the trocar introducer technique with peel-away sheath. *Surg Gynecol Obstet 173:* 490-494.

Kassell NF, Dumont AS 2006. Randomized controlled trials in surgery: comic opera no more? *J Thorac Cardiovasc Surg 132:* 243-244.

Kim YS, Oh YL, Shon YW, Yang HD, Lee SI, Cho EY, Choi CS, Seo GS, Choi SC, Na YH 2006. A case of buried bumper syndrome in a patient with a balloon-tipped percutaneous endoscopic gastrostomy tube. *Endoscopy 38 Suppl 2:* E41-42.

Kiser AC, Inglis G, Nakayama DK 1999. Primary percutaneous endoscopic button gastrostomy: a modification of the "push" technique. *J Am Coll Surg 188:* 704-706.

Kozarek RA, Ball TJ, Ryan JA, Jr 1986. When push comes to shove: a comparison between two methods of percutaneous endoscopic gastrostomy. *Am J Gastroenterol 81:* 642-646.

Laasch HU, Martin DF 2007. Radiologic gastrostomy. *Endoscopy 39:* 247-255.

Lee TH, Lin JT 2008. Clinical manifestations and management of buried bumper syndrome in patients with percutaneous endoscopic gastrostomy. *Gastrointest Endosc 68:* 580-584.

Lipp A, Lusardi G 2006. Systemic antimicrobial prophylaxis for percutaneous endoscopic gastrostomy. *Cochrane Database Syst Rev:* CD005571.

Ljungdahl M, Sundbom M 2006. Complication rate lower after percutaneous endoscopic gastrostomy than after surgical gastrostomy: a prospective, randomized trial. *Surg Endosc 20:* 1248-1251.

Lorentzen T, Nolsoe CP, Adamsen S 2007. Percutaneous radiologic gastrostomy with a simplified gastropexy technique under ultrasonographic and fluoroscopic guidance: experience in 154 patients. *Acta Radiol 48:* 13-19.

Ma MM, Semlacher EA, Fedorak RN, Lalor EA, Duerksen DR, Sherbaniuk RW, Chalpelsky CE, Sadowski DC 1995. The buried gastrostomy bumper syndrome: prevention and endoscopic approaches to removal. *Gastrointest Endosc 41:* 505-508.

Maetani I, Tada T, Ukita T, Inoue H, Sakai Y, Yoshikawa M 2003. PEG with introducer or pull method: a prospective randomized comparison. *Gastrointest Endosc 57:* 837-841.

McGarr SE, Kirby DF 2007. Percutaneous endoscopic gastrostomy (PEG) placement in the overweight and obese patient. *JPEN J Parenter Enteral Nutr 31:* 212-216.

McKee M, Britton A, Black N, McPherson K, Sanderson C, Bain C 1999. Methods in health services research. Interpreting the evidence: choosing between randomised and non-randomised studies. *BMJ 319:* 312-315.

Meine G, Lukashok H, Mello G, Mansur G, Guimarães D, Carvalho R 2007. Buried Bumper Syndrome as a complication of Percutaneous Endoscopic Gastrostomy in cancer patients: The Brazilian Experience. *Digestive Endoscopy 19:* 22-25.

Miller RE, Castlemain B, Lacqua FJ, Kotler DP 1989. Percutaneous endoscopic gastrostomy. Results in 316 patients and review of literature. *Surg Endosc 3:* 186-190.

Miller RE, Kummer BA, Tiszenkel HI, Kotler DP 1986. Percutaneous endoscopic gastrostomy. Procedure of choice. *Ann Surg 204:*543-545.

Minard G. The history of surgically placed feeding tubes 2006. *Nutr Clin Pract 21:* 626-633.

Morioka RH, Mikami G, Onozato ML, TaclaJúnior O, Godoy AQ, Fonseca PC, Komatsu S 1995. Gastrostomia endoscópica percutânea: uma técnica simples e efetiva de nutrição enteral. *Rev Col Bras Cir 22:* 11-16.

Morton RP, Crowder VL, Mawdsley R, Ong E, Izzard M 2009. Elective gastrostomy, nutritional status and quality of life in advanced head and neck cancer patients receiving chemoradiotherapy. *ANZ J Surg 79:* 713-718.

Oakley RJ, Donnelly R, Freeman L, Wong T, McCarthy M, Calman F, O'Connell M, Jeannon JP, Simo R 2009. An audit of percutaneous endoscopic gastrostomy insertion in patients undergoing treatment for head and neck cancer: reducing the incidence of peri-operative airway events by the introduction of a tumour assessment protocol. *Ann R Coll Surg Engl 91:* 249-254.

Petersen TI, Kruse A 1997. Complications of percutaneous endoscopic gastrostomy. *Eur J Surg 163:* 351-356.

Piantadosi S 2005. Contexts for clinical trials. In Piantadosi S, editor. *Clinical Trials: a methodologic perspective.* Hoboken, NJ, John Wiley & Sons, p. 88.

Piantadosi S 2006. Improving the quality of clinical trials in surgery. *J Thorac Cardiovasc Surg 132:* 247-248.

Preclik G, Grune S, Leser HG, Lebherz J, Heldwein W, Machka K, Holstege A, Kern WV 1999. Prospective, randomised, double blind trial of prophylaxis with single dose of co-amoxiclav before percutaneous endoscopic gastrostomy. *BMJ 319:* 881-884.

Preshaw RM 1981. A percutaneous method for inserting a feeding gastrostomy tube. *Surg Gynecol Obstet 152:* 658-660.

Ridgway PF, Darzi AW 2002. Placebos and standardising new surgical techniques. *BMJ 325:* 560.

Riley DA, Strauss M 1992. Airway and other complications of percutaneous endoscopic gastrostomy in head and neck cancer patients. *Ann Otol Rhinol Laryngol 101:* 310-313.

Robertson FM, Crombleholme TM, Latchaw LA, Jacir NN 1996. Modification of the "push" technique for percutaneous endoscopic gastrostomy in infants and children. *J Am Coll Surg 182:* 215-218.

Russell TR, Brotman M, Norris F 1984. Percutaneous gastrostomy. A new simplified and cost-effective technique. *Am J Surg 148:* 132-137.

Ryan JM, Hahn PF, Boland GW, McDowell RK, Saini S, Mueller PR 1997. Percutaneous gastrostomy with T-fastener gastropexy: results of 316 consecutive procedures. *Radiology 203:* 496-500.

Sabnis A, Liu R, Chand B, Ponsky J 2006. SLiC technique. A novel approach to percutaneous gastrostomy. *Surg Endosc 20:* 256-262.

Sacks BA, Glotzer DJ 1979. Percutaneous reestablishment of feeding gastrostomies. *Surgery 85:* 575-576.

Sade RM 2006. Reports of clinical trials: ethical aspects. *J Thorac Cardiovasc Surg 132:* 245-246.

Saito M, Muto M, Yano T, Kojima T, Minashi K, Ohtsu A, Yoshida S 2007. Gastropexy reduces severe adverse events after percutaneous endoscopic gastrostomy (PEG). *Gastrointest Endosc 65:* AB163.

Sartori S, Trevisani L, Nielsen I, Tassinari D, Ceccotti P, Abbasciano V 2003. Longevity of silicone and polyurethane catheters in long-term enteral feeding via percutaneous endoscopic gastrostomy. *Aliment Pharmacol Ther 17:* 853-856.

Saunders JR, Jr., Brown MS, Hirata RM, Jaques DA 1991. Percutaneous endoscopic gastrostomy in patients with head and neck malignancies. *Am J Surg 162:* 381-383.

Schapiro GD, Edmundowicz SA 1996. Complications of percutaneous endoscopic gastrostomy. *Gastrointest Endosc Clin N Am 6:* 409-422.

Schrag SP, Sharma R, Jaik NP, Seamon MJ, Lukaszczyk JJ, Martin ND, Hoey BA, Stawicki SP 2007. Complications related to percutaneous endoscopic gastrostomy (PEG) tubes. A comprehensive clinical review. *J Gastrointestin Liver Dis 16:* 407-418.

Schurink CA, Tuynman H, Scholten P, Arjaans W, Klinkenberg-Knol EC, Meuwissen SG, Kuipers EJ 2001. Percutaneous endoscopic gastrostomy:

complications and suggestions to avoid them. *Eur J Gastroenterol Hepatol 13:* 819-823.

Sédillot CE 1849. Opération de gastro-stomie, pratiquée pour la première fois le 13 novembre 1849. *Gaz Méd Strasbourg 9:* 566.

Seldinger SI 1953. Catheter replacement of the needle in percutaneous arteriography; a new technique. *Acta radiol 39:* 368-376.

Shastri YM, Hoepffner N, Tessmer A, Ackermann H, Schroeder O, Stein J 2008. New introducer PEG gastropexy does not require prophylactic antibiotics: multicenter prospective randomized double-blind placebo-controlled study. *Gastrointest Endosc 67:* 620-628.

Stamm M 1894. Gastrostomy by a new method. *Med News 65:* 324-326.

Tao HH, Gillies RR 1983. Percutaneous feeding gastrostomy. *AJR Am J Roentgenol 141:* 793-794.

Thornton FJ, Fotheringham T, Haslam PJ, McGrath FP, Keeling F, Lee MJ 2002. Percutaneous radiologic gastrostomy with and without T-fastener gastropexy: a randomized comparison study. *Cardiovasc Intervent Radiol 25:* 467-471.

Tiruvoipati R, Balasubramanian SP, Atturu G, Peek GJ, Elbourne D 2006. Improving the quality of reporting randomized controlled trials in cardiothoracic surgery: the way forward. *J Thorac Cardiovasc Surg 132:* 233-240.

Toyama Y, Usuba T, Son K, Yoshida S, Miyake R, Ito R, Tsuboi K, Kashiwagi H, Tajiri H, Yanaga K 2007. Successful new method of extracorporeal percutaneous endoscopic gastrostomy (E-PEG). *Surg Endosc 21:* 2034-2038.

Tucker AT, Gourin CG, Ghegan MD, Porubsky ES, Martindale RG, Terris DJ 2003. 'Push' versus 'pull' percutaneous endoscopic gastrostomy tube placement in patients with advanced head and neck cancer. *Laryngoscope 113:* 1898-1902.

Usuba T, Suzuki Y, Kuramochi A, Tajiri H, Yanaga K 2007. Analysis of buried bumper syndrome after percutaneous endoscopic gastrostomy due to use of a button-type kit. *Digestive Endoscopy 19:* 18-21.

Van Den Hazel SJ, Mulder CJ, Den Hartog G, Thies JE, Westhof W 2000. A randomized trial of polyurethane and silicone percutaneous endoscopic gastrostomy catheters. *Aliment Pharmacol Ther 14:* 1273-1277.

Verneuil AAS 1876. Sur une opération de gastrostomie. *Bull Acad Méd 5:* 1016-1023.

Wills JS, Oglesby JT 1986. Controlled percutaneous gastrostomy: nylon T-fastener for fixation of the anterior gastric wall. *Radiology 160:* 278.

Wills JS, Oglesby JT 1983. Percutaneous gastrostomy. *Radiology 149:* 449-453.

Wong R, Ponsky J 2000. Percutaneous endoscopic gastrostomy. In Sivak MV, editor. Gastroenterologic endoscopy. Philadelphia: W.B. Saunders Company: p. 813.

Yamazaki T, Sakai Y, Hatakeyama K, Hoshiyama Y 1999. Colocutaneous fistula after percutaneous endoscopic gastrostomy in a remnant stomach. *Surg Endosc 13:* 280-282.

PROTOCOLO CEP/ACCG Nº 050/07 **Goiânia, 07/02/2008**

INVESTIGADOR (A) RESPONSÁVEL (ES): Dr. Paulo Moacir de Oliveira Campoi

TÍTULO: Gastrostomia Endoscópica Percutânea

Área Temática: Grupo III
Local de Realização: Hospital Araújo Jorge – Setor de Endoscopia Digestiva

Informamos que o Comitê de Ética em Pesquisa da ACCG **analisou e aprovou** o projeto de Pesquisa acima referido, juntamente com os documentos apresentados e os mesmos foram considerados em acordo com os princípios éticos vigentes.

*Recomendamos:

Esclarecimento quanto à informação de que o levantamento será dos casos de gastrostomias endoscópicas percutâneas realizadas até maio de 2008, portanto, não se trata de estudo retrospectivo.

Não há necessidade de aguardar o parecer da CONEP – Comissão Nacional de Ética em Pesquisa para iniciar a pesquisa.

O Pesquisador responsável deverá encaminhar ao CEP/ACCG, relatórios trimestrais do andamento da pesquisa, encerramento, conclusão(ões) e publicação(ões).

DR. GERALDO SILVA QUEIROZ
Coordenador do CEP/ACCG

PROTOCOLO CEPACCG Nº 041/10 **Goiânia, 03/09/2010**

INVESTIGADOR (A) RESPONSÁVEL (EIS): Dr. Paulo Moacir de Oliveira Campos

TÍTULO: "Estudo comparativo das complicações infecciosas de duas técnicas distintas de fixação gástrica durante a realização de gastrostomia endoscópica percutânea".

Área Temática: Grupo III

Área de Conhecimento: Ciências da Saúde/Medicina

Local de Realização: Setor de Endoscopia Digestiva/ Hospital Araújo Jorge/ACCG

Informamos que o Comitê de Ética em Pesquisa da ACCG **analisou e aprovou** o projeto de Pesquisa acima referido, juntamente com os documentos apresentados e os mesmos foram considerados em acordo com os princípios éticos vigentes.

Não há necessidade de aguardar o parecer da CONEP – Comissão Nacional de Ética em Pesquisa para iniciar a pesquisa *(Resolução 340/2004 – item IV.3)*.

O Pesquisador responsável deverá encaminhar ao CEPACCG, **relatórios semestrais** do andamento da pesquisa, encerramento, concluído (dos) e publicação (ões).

O CEP/ACCG pode, a qualquer momento, fazer escolha aleatória de estudo em desenvolvimento para avaliação e verificação do cumprimento das normas da Resolução 196/96 (*Manual Operacional Para Comitês de Ética em pesquisa – Item 13*).

Dra. Juliana Carrijo Dourado Pinesi
Coordenadora do CEP/ACCG

ACCG
ASSOCIAÇÃO DE COMBATE AO CÂNCER EM GOIÁS
62) 3078-7000 | 3243-7000
Rua 230, nº 206, St. Universitário
Goiânia - Goiás - Brasil - CEP 74.605-070
www.accg.org.br

PROTOCOLO CEPACCG Nº 060/06 **Goiânia, 14/09/2006**

INVESTIGADOR (A) RESPONSÁVEL (ES): Dr. Paulo Moacir de Oliveira Campoli

TÍTULO: Estudo comparativo entre dois tipos de sondas usadas na realização de gastrostomia endoscópica percutânea

Área Temática: Grupo III
Local de Realização: Hospital Araújo Jorge/ACCG – Endoscopia Digestiva

Informamos que o Comitê de Ética em Pesquisa da ACCG **analisou e aprovou sem recomendação**, o projeto de Pesquisa acima referido, juntamente com os documentos apresentados.

***Recomendamos:**

Apresentação de maiores esclarecimentos sobre os critérios que serão considerados como melhor ou pior na determinação das reações adversas provocadas pelas sondas com relação às reações cutâneas.

- ✓ O pesquisador responsável não necessita aguardar o parecer da CONEP – Comissão Nacional de Ética em Pesquisa, para iniciar a pesquisa neste centro de estudo.
- ✓ Pesquisador responsável deverá encaminhar ao CEPACCG, relatórios trimestrais do andamento da pesquisa, encerramento, conclusão(ões) e publicação(ões).

DR. GERALDO SILVA QUEIROZ
Coordenador do CEPACCG

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Através do presente documento, você está sendo convidado a participar, de forma voluntária, de um protocolo de tratamento cujas características estão abaixo listadas:

1. O seu médico nos solicitou para providenciarmos a colocação de uma sonda gástrica para que você possa se alimentar enquanto realiza o tratamento da sua doença.
2. Esta sonda gástrica será colocada com uso de sedação e anestesia local, utilizando os recursos da Endoscopia Digestiva.
3. Você está sendo convidado a participar de um estudo que pretende avaliar dois tipos diferentes de sondas gástricas. Mesmo sendo feitas de materiais diferentes, as duas sondas são usadas normalmente neste tipo de situação, e o que se pretende estudar é se existem diferenças entre elas no que diz respeito a durabilidade, reações locais e custos.
4. Caso você concorde em participar do estudo, será realizado um sorteio para escolher um dos dois tipos de sonda gástrica, para ser usada na sua cirurgia.
5. Caso você não concorde em participar do estudo, a sua cirurgia será realizada normalmente, com uso da sonda gástrica que já vem sendo usada há vários anos no nosso Hospital.
6. Se você concordar em participar do estudo, você estará contribuindo para que possamos saber qual sonda gástrica é mais durável, qual tem menos reação local e qual delas tem menor custo, sem que isso venha a trazer qualquer dano à sua saúde pois ambas as sondas gástricas são adequadas para uso nesta situação.
7. A você está assegurado o direito de receber respostas a quaisquer perguntas ou esclarecimentos sobre dúvidas acerca do procedimento, riscos, benefícios ou de outros temas relacionados ao tratamento.
8. A você está garantida a liberdade de retirar o consentimento a qualquer momento e dessa forma deixar de participar desta proposta de tratamento, sem que isto traga prejuízo à continuidade do seu tratamento.
9. Você tem a garantia de não ser identificado quando da divulgação dos resultados e as informações obtidas serão utilizadas apenas para fins científicos vinculados ao presente protocolo de tratamento.
10. A você está garantida a disponibilidade de tratamento médico e indenização, conforme estabelece a legislação, caso sejam comprovados danos à sua saúde diretamente causados por este protocolo de tratamento.

O Médico Responsável por este Protocolo de Tratamento é o Dr. Paulo Moacir de Oliveira Campoli (telefone 3243-7125) e este documento foi revisado e aprovado pelo Comitê de Ética em Pesquisa desta Instituição.

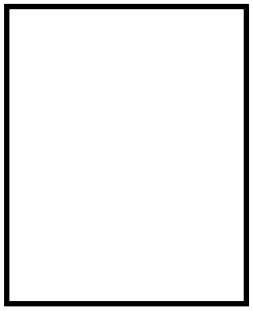
CONSENTIMENTO DA PARTICIPAÇÃO DO PACIENTE NO PROTOCOLO DE

TRATAMENTO

Eu, _____, matrícula no. _____, abaixo assinado, concordo em participar do Protocolo de Tratamento acima descrito, de forma voluntária. Declaro que fui devidamente informado e esclarecido pelo Médico Responsável, Dr. Paulo Moacir de Oliveira Campoli, sobre as vantagens e sobre os riscos do tratamento proposto. Declaro também que me foi garantido o direito de retirar o consentimento a qualquer momento, sem que isto leve a qualquer penalidade ou interrupção do meu tratamento.

Goiânia, ____ / ____ / _____.

_____
Nome e Assinatura do Paciente ou do Responsável

Assinatura Dactiloscópica: 

_____
Nome e Assinatura do Médico Responsável

TESTEMUNHAS

Presenciamos a solicitação de Consentimento sobre o Protocolo de Tratamento e testemunhamos o aceite do paciente em participar.

Testemunhas:

Nome: _____

Assinatura: _____

Nome: _____

Assinatura: _____

Preview

From: digestive_endoscopy@jges.or.jp

To: paulomar@ih.com.br

CC:

Subject: Digestive Endoscopy - Decision on Manuscript ID:DEN-2010-0125.R1

Body: @@date to be populated upon sending@@

Dear Dr. Paulo Campolin

It is a pleasure to accept your manuscript entitled "Clinical trial: a randomized study comparing the durability of silicone and latex percutaneous endoscopic gastrostomy (PEG) tubes" in its current form for publication in Digestive Endoscopy. The comments of the reviewer(s) who reviewed your manuscript are included at the foot of this letter if any.

You are required to sign an Exclusive License Form. In signing the form it is assumed that authors have obtained permission to use any copyrighted or previously published material. You must read and agree to the conditions outlined in the form, and must sign the form or agree that the corresponding author can sign on their behalf. Your article cannot be published until a signed form has been received. You can download the form from http://www.blackwellpublishing.com/pdf/den_off.pdf Please send the form to the Editorial Office at the address below as soon as possible.

Thank you for your fine contribution. On behalf of the Editors of Digestive Endoscopy, I look forward to your continued contributions to the Journal.

Sincerely,

Prof. Hiromitsu Saisho
Editor-in-Chief
Digestive Endoscopy

Japan Gastroenterological Endoscopy Society
3-23 Kanda Ogawa-machi
Chiyoda-ku
Tokyo 101-0052
Japan

Date Sent: 11-Jun-2010

Title: Successful new method of extracorporeal percutaneous endoscopic gastrostomy (E-PEG)

Author: Yoichi Toyama

Publication: Surgical Endoscopy

Publisher: Springer

Date: Jan 1, 2007

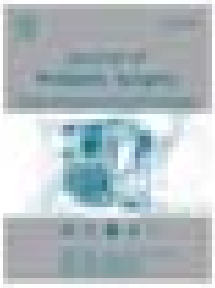
Order Completed

Thank you very much for your order.

This is a License Agreement between Paulo Campoli ("You") and Springer ("Springer"). The license consists of your order details, the terms and conditions provided by Springer, and the payment terms and conditions.

Get the printable license.

License number	2944071122944
License date	Nov 09, 2010
Licensed content publisher	Springer
Licensed content publication	Surgical Endoscopy
Licensed content title	Successful new method of extracorporeal percutaneous endoscopic gastrostomy (E-PEG)
Licensed content author	Yoichi Toyama
Licensed content date	Jan 1, 2007
Volume number	21
Issue number	11
Type of use	Thesis/Dissertation
Portion	Figures
Author of this Springer article	No
Title of your thesis / dissertation	Validation of a new technical variant of gastropexy in patients undergoing percutaneous endoscopic gastrostomy
Expected completion date	Mar 2011
Estimated size(pages)	88
Total	0.00 USD



Title: Gastrostomy without laparotomy: A percutaneous endoscopic technique

Author: Michael W.L. Gauderer, Jeffrey L. Ponsky, Robert J. Izant Jr.

Publication: Journal of Pediatric Surgery

Publisher: Elsevier

Date: December 1980

Order Completed

Thank you very much for your order.

This is a License Agreement between Paula Campoli ("You") and Elsevier ("Elsevier"). The license consists of your order details, the terms and conditions provided by Elsevier, and the payment terms and conditions.

Get the printable license.

License Number	2944021285531
License date	Nov 05, 2014
Licensed content publisher	Elsevier
Licensed content publication	Journal of Pediatric Surgery
Licensed content title	Gastrostomy without laparotomy: A percutaneous endoscopic technique
Licensed content author	Michael W.L. Gauderer, Jeffrey L. Ponsky, Robert J. Izant Jr.
Licensed content date	December 1980
Licensed content volume number	15
Licensed content issue number	6
Number of pages	4
Type of Use	reuse in a thesis/dissertation
Intended publisher of new work	other
Portion	figures/tables/illustrations
Number of figures/tables/illustrations	4
Format	print
Are you the author of this Elsevier article?	No
Will you be translating?	No
Order reference number	
Title of your thesis/dissertation	Validation of a new technical variant of gastropexy in patients undergoing percutaneous endoscopic gastrostomy
Expected completion date	Mar 2015
Estimated size (number of pages)	99
Elsevier VAT number	GB 494 6272 12
Permissions price	0.00 USD
Value added tax 0.0%	0.0 USD | 0.0 GBP
Total	0.00 USD