

NOTA TÉCNICA Nº 2864/2022- NAT-JUS/SP

1. Identificação do solicitante

- 1.1. Solicitante: [REDACTED]
- 1.2. Origem: 4ª Vara Federal de Ribeirão Preto
- 1.3. Processo nº 5008009-96.2022.4.03.6102
- 1.4. Data da Solicitação: **07/07/2023**
- 1.5. Data da Resposta: **17/07/2023**

2. Paciente

- 2.1. Data de Nascimento/Idade: 17/02/1961- 62 anos
- 2.2. Sexo: Feminino
- 2.3. Cidade/UF: Ribeirão Preto/SP
- 2.4. Histórico da doença: Incontinência Fecal Grave

3. Quesitos formulados pelo(a) Magistrado(a)

4. Descrição da Tecnologia

- 4.1. Tipo da tecnologia: PROCEDIMENTO
NEUROMODULAÇÃO/ESTIMULAÇÃO NERVOSA SACRAL – IMPLANTE DE MARCAPASSO INTERSTIM

5. Discussão e Conclusão

- 5.1. Evidências sobre a eficácia e segurança da tecnologia:

A incontinência fecal é definida como a perda involuntária de fezes sólidas ou líquidas. O manejo inicial da incontinência fecal consiste em cuidados de suporte e terapia médica. Os cuidados de suporte incluem evitar alimentos ou atividades conhecidas por piorar os sintomas e manter a higiene da pele perianal. Utiliza-se agente de volume e antidiarreicos em pacientes com incontinência fecal devido a diarreia – a paciente já faz uso diário de loperamida.

O encaminhamento para um gastroenterologista deve ser considerado em pacientes que não respondem ao tratamento inicial. Esses pacientes devem passar por avaliação adicional (por exemplo, manometria anorretal, ultrassonografia/ressonância magnética endorretal) para detectar anormalidades funcionais e estruturais que causam incontinência fecal e orientar o tratamento subsequente. Para pacientes que não respondem ao tratamento inicial, as opções incluem biofeedback, agente de volume anal injetável, estimulação do nervo sacral e esfínteroplastia anal. A terapia de biofeedback para incontinência fecal só deve ser considerada em pacientes com evidência manométrica de fraqueza do esfínter anal externo ou diminuição da

capacidade de perceber distensão retal devido a lesão nervosa. A paciente realizou biofeedback sem resposta.

Injeções anais de dextranômero estabilizado em ácido hialurônico para pacientes com incontinência fecal passiva e esfínteroplastia anal para pacientes com lesão são reconhecidas do esfínter anatômico logo após o parto vaginal, o que não vem a ser o caso pois paciente tem tal sintoma associado a colite actínica após tratamento de neoplasia de ovário. A estimulação do nervo sacral para pacientes que não são candidatos a agentes injetáveis de volume anal ou esfínteroplastia ou nos quais falharam. Não há relato de esfínteroplastia. A derivação fecal com colostomia ou ileostomia deve ser reservada para pacientes com sintomas intratáveis que falharam no tratamento não cirúrgico e que falharam ou não são candidatos a intervenções cirúrgicas minimamente invasivas. A graciloplastia dinâmica e os dispositivos de esfínter anal artificial estão associados a morbidade significativa e, portanto, devem ser usados apenas para tratar a incontinência fecal refratária.

5.2. Benefício/efeito/resultado esperado da tecnologia:

A estimulação do nervo sacral para pacientes que não são candidatos a biofeedback ou esfínteroplastia, ou nos quais falharam. A estimulação elétrica das raízes nervosas sacrais pode melhorar a continência fecal em pacientes com defeitos do esfínter anal e naqueles com esfíncteres anais estruturalmente intactos. O mecanismo exato de ação da estimulação do nervo sacral não é conhecido, mas seus efeitos podem ocorrer no nível aferente pélvico ou central, em vez de neuroestimulação motora periférica primária. A estimulação do nervo sacral parece ser particularmente eficaz em pacientes com distúrbios neurológicos e naqueles com incontinência fecal após ressecção anterior inferior. Envolve a colocação de um eletrodo temporário no forame sacral para fornecer estimulação elétrica de baixo grau. Os pacientes que respondem a um teste de duas semanas são submetidos à colocação de um eletrodo permanente conectado por via subcutânea a um estimulador embutido.

A estimulação do nervo sacral pode melhorar a continência fecal, melhorando as pressões de repouso e compressão do esfínter anal, sensação retal e aumentando as sequências de propagação colônica retrógrada. As complicações mais comuns incluem deslocamento do eletrodo (12 %) e infecção (3 %). Após a implantação do estimulador, um número significativo de pacientes necessitará de revisão cirúrgica para várias indicações (por exemplo, falha do dispositivo, deslocamento ou quebra do eletrodo ou esgotamento da bateria).

Em um estudo randomizado que incluiu 120 pacientes com incontinência fecal, os pacientes foram designados para estimulação do nervo sacral ou terapia médica ideal consistindo em exercícios do assoalho pélvico, agentes de volume e mudanças na dieta. O estimulador permanente do nervo sacral foi colocado em 54 dos 60 pacientes randomizados que demonstraram melhora durante um período experimental temporário. Em contraste com o grupo controle, no qual não houve melhora

significativa no número de episódios de continência fecal e nos escores de qualidade de vida da incontinência fecal aos 12 meses de acompanhamento, o uso do estimulador do nervo sacral foi associado a um aumento significativo em ambos em comparação com a linha de base. Além disso, 25 pacientes (47 %) submetidos à estimulação do nervo sacral alcançaram continência completa. As complicações incluíram dor no local do implante (6 %), seroma (2 %) e formigamento na região vaginal (9 %). Não houve complicações sépticas que exigissem explantação do eletrodo.

Em uma coorte multicêntrica prospectiva de 120 pacientes que receberam implantação de um estimulador de nervo sacral, 86 % alcançaram redução superior a 50 % em episódios de incontinência por semana e 40 % não tiveram incontinência fecal em três anos de acompanhamento. Os eventos adversos mais comuns incluíram dor no local do implante, parestesia, alteração na sensação de estimulação e infecção (28, 15 12 e 10 %, respectivamente). Em outro estudo, durante um acompanhamento médio de 49 meses, 36 de 87 pacientes (41 %) submetidos à implantação do estimulador precisaram de revisão cirúrgica. Os motivos da revisão incluíram infecção (quatro pacientes), deslocamento do eletrodo (dois pacientes), quebra do eletrodo (dois pacientes), disfunção devido ao aumento da impedância (quatro pacientes), dor com estimulação (sete pacientes), esgotamento da bateria (oito pacientes), e perda parcial ou total da eficácia clínica (nove pacientes).

A estimulação do nervo tibial posterior (PTNS) também foi associada a melhorias de curto prazo na incontinência fecal em várias séries. No entanto, em um estudo randomizado no qual 227 pacientes com incontinência fecal foram designados para PTNS ou estimulação simulada, não houve redução significativa no número de episódios de incontinência fecal com PTNS. No entanto, estudos adicionais são necessários para avaliar a eficácia a longo prazo da PTNS e para determinar se existem subgrupos de pacientes que podem se beneficiar do tratamento.

5.3. Parecer

Favorável

Desfavorável

5.4. Conclusão Justificada:

Paciente com antecedentes de neoplasia ovariana com colite actínica – provável contra indicação a esfinteroplastia, e incontinência fecal intratável, há indicação do procedimento a fim de dar qualidade de vida a paciente.

Justifica-se a alegação de urgência, conforme definição de urgência e emergência do CFM?

SIM, com potencial risco de vida

SIM, com risco de lesão de órgão ou comprometimento de função

() NÃO

5.5. Referências bibliográficas:

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5.6. Outras Informações:

Considerações NAT-Jus/SP: A autoria do presente documento não é divulgada por motivo de preservação do sigilo.

Equipe NAT-Jus/SP