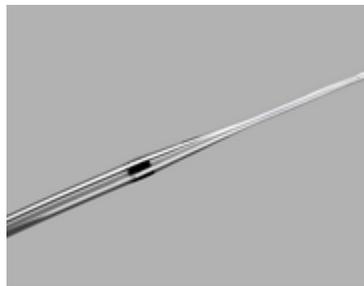


LE TRAITEMENT ENDOSCOPIQUE DU REFLUX GASTRO-OESOPHAGIEN

Héla ELLOUMI
Hôpital Habib Thameur

- Traitement du RGO compliqué
(sténose, anneau de Schatzki, EBO)
- Traitement du RGO non compliqué

DILATATION- STÉNOSE PEPTIQUE



Ø 5-20mm

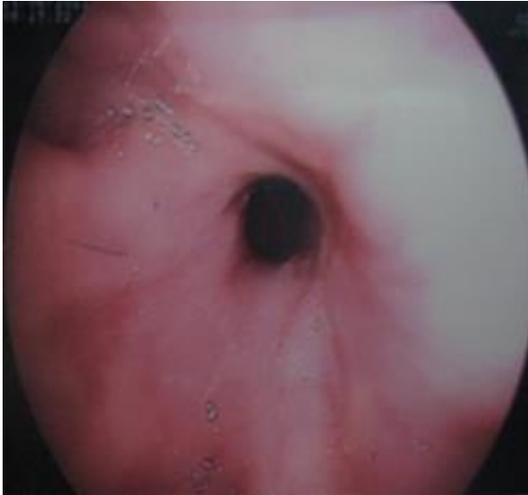
Bougies de
Savary-Gilliard
en polyvinyl



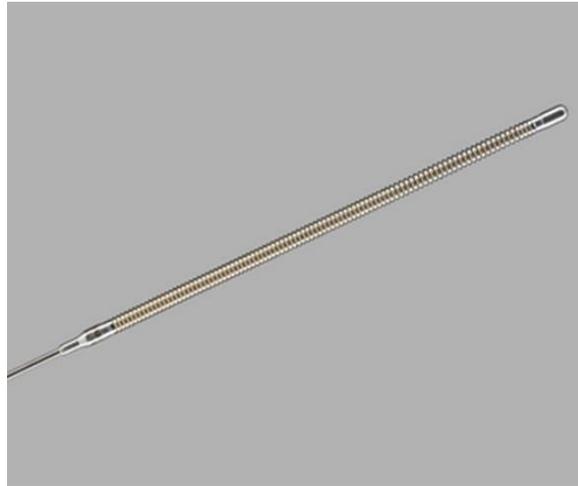
Ballonnet hydrostatique
type CRE Wireguided
(Boston*)
en polyéthylène

Ø: 4-20 mm-
L : 5- 8 cm
P: 3-8 ATM

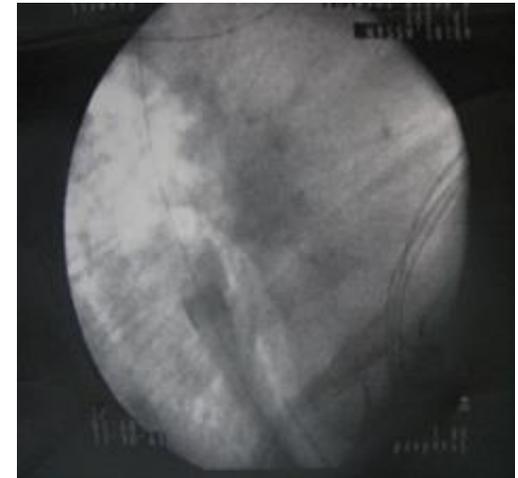
Dilatation- Bougies de Savary-Gilliard



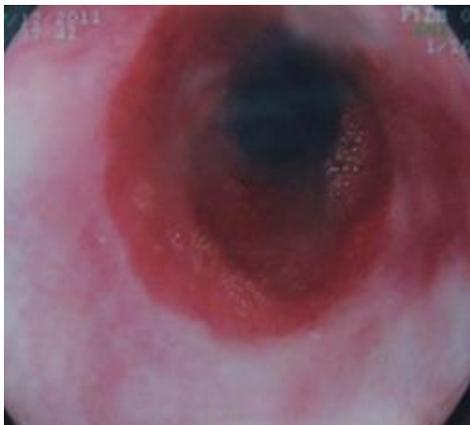
Caractérisation de la sténose



Fil guide métallique de savary

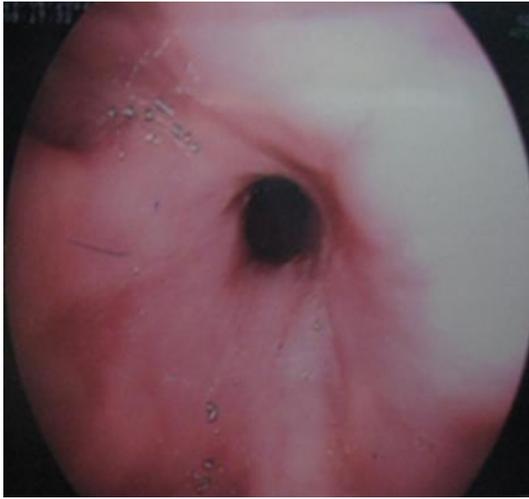


Contrôle sous scopie



Contrôle en fin de procédure:
Saignement

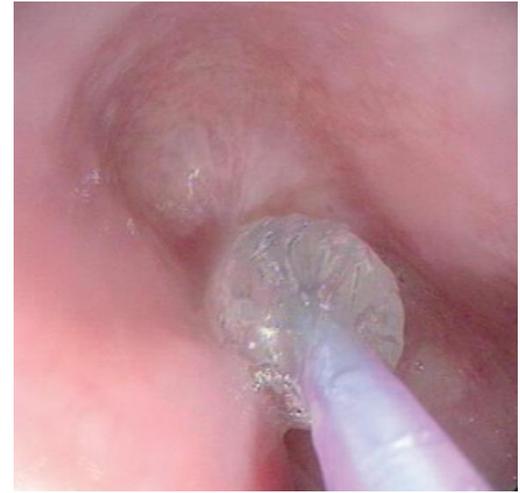
Dilatation hydrostatique



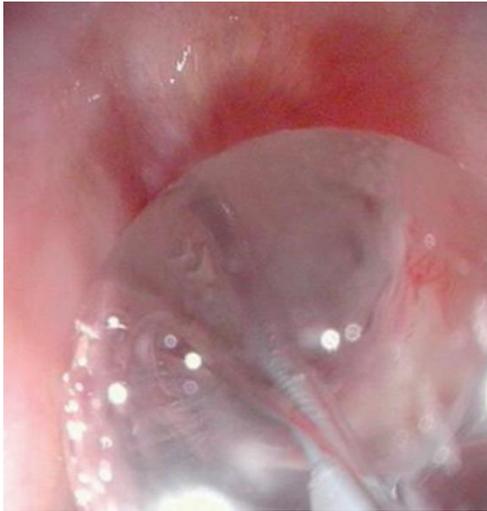
La sténose



Ballonnet TTS



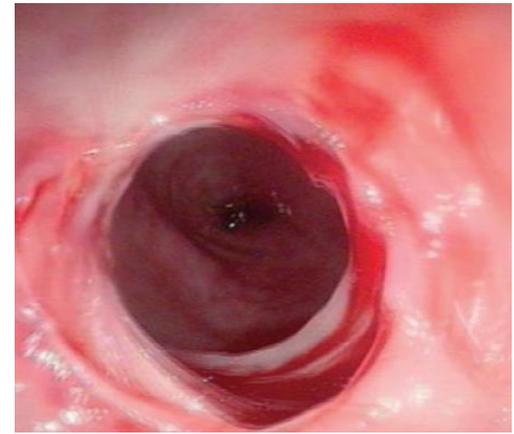
Partie médiane du ballonnet à cheval sur la sténose



Dilatation progressive



Contrôle scopique



Contrôle endoscopique
Fin de procédure

Bougie versus ballon

- IPP +++
- Perforation : 0,4 à 1 %- **[Règle de 3/session]**
- pas de différence d'efficacité ou de complication
- Efficacité moyenne après 3 séances de dilatation > 80%
- Sténose réfractaire : nécessité au max 5 séances/2sem
- Injection de stéroïdes
- Deux études randomisées (stéroïde +dilat) vs dilat seule
 - *Ramage*: nouvelles dilatations 13 % vs 60 %
 - *Dunne*: diminution du nombre de dilatation 6 à 2

Saeed ZA GIE 1995; 41:189-95; Scolapio GIE 1999; 50:13-7

Dunne D Gastroenterology 1999; Ramage Jr JAm J Gastroenterol 2005

Sténose peptique



Dilatation (Savary ou ballonnet)
(max: 16-18mm)/(max:5 sessions)

Échec



Dilatation combinée avec injection stéroïdes
(4 quadrants: Trimacinolone acetate: Nasacort*)
(max: 3 sessions)

Échec



Prothèse totalement couverte ou biodégradable

Échec



Chirurgie

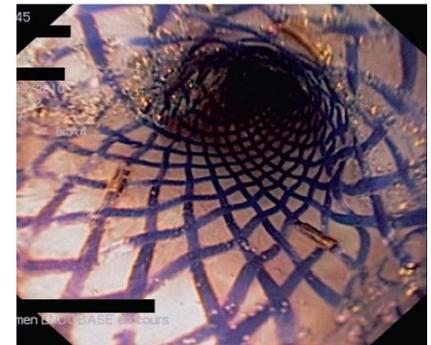
PROTHÈSES- STÉNOSE PEPTIQUE

- **Prothèses métalliques couvertes**

- 10 patients avec sténoses réfractaires :
- 21 % n'ont pas eu besoin d'une nouvelle intervention après le retrait de la prothèse,
- 34 % migration

- **Prothèses biodégradables**

- 13 patients, 59 prothèses biodégradables posées médiane sans dysphagie était de 90j
- 25 % des patients étaient asymptomatiques à 6 M
- Après la pose d'une deuxième prothèse, la période médiane sans dysphagie était de 55 jours et de 106 jours après la troisième.



Anneau de Schatski



- Dilatation au ballonnet hydrostatique
(16-20mm nécessaire)
- Incision radiaire
aiguille à pré-coupe (kneedle knife®)

Amélioration de la dysphagie dans 85% des cas

Sténose peptique

Dilatation (Savary ou ballonnet)
(max: 16-18mm)/(max:5 sessions)

Échec

Dilatation combinée avec injection stéroïdes
(4 quadrants: Trimacinolone acetate: Nasacort*)
(max: 3 sessions)

Échec

Prothèse totalement couverte ou biodégradable

Échec

Chirurgie

Schatski

Incision
radiaire

TRAITEMENT DU RGO NON COMPLIQUÉ

- Progrès ces 20 dernières années
- Développement technologique de la chirurgie laparoscopique
- Alternative au traitement chirurgical
 - Réalisation plus simple
 - Moins invasives
 - Moins d'effets secondaires
 - Réalisation en ambulatoire
 - Possibilité de répéter le traitement
 - Potentiellement réversible

Moyens

- ~ 10 méthodes en évaluation clinique ou au stade expérimental
- Classées en 3 catégories

Sutures
endoscopiques

Radiofréquence

Techniques
d'injections

Stretta

Endocinch

ESD

Plicator

Esophyx

Enteryx

Gatekeeper



Indications



Indications

- **Dépendance aux IPP**

Sans HH > 2 cm

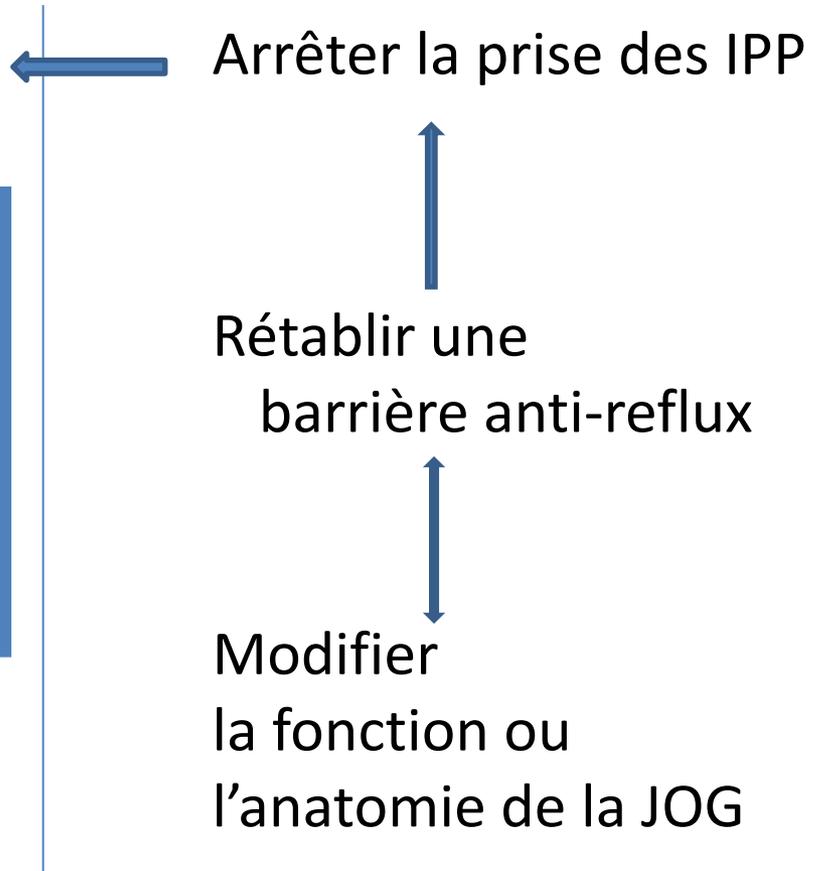
Sans muqueuse de Barrett

Sans œsophagite sévère

Arrêter la prise des IPP

Rétablir une
barrière anti-reflux

Modifier
la fonction ou
l'anatomie de la JOG



LA RADIOFREQUENCE

Hyperthermie par radiofréquence

- Principe: Induire des lésions thermiques du SIO et du cardia proximal
- Conséquence: Epaissement pariétal par fibrose extensive de la paroi et une destruction des canaux nerveux à l'origine des relaxations transitoires du SIO

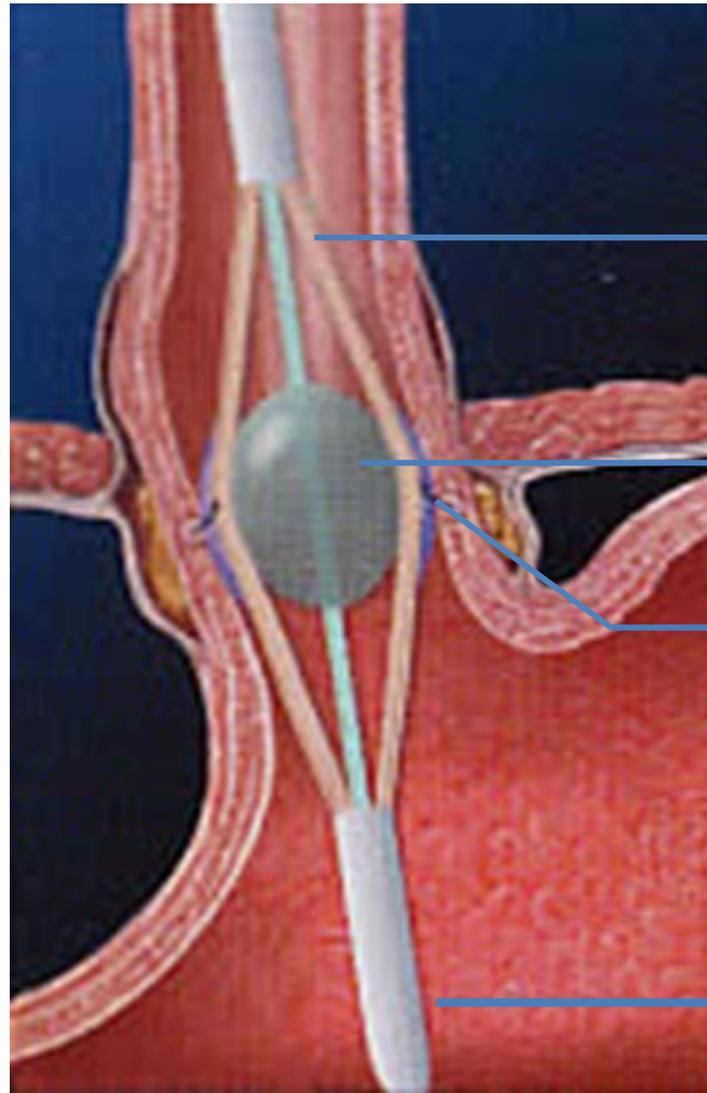
Stretta

Radiofréquence

CURON STRETТА Sunnyvale, CA USA



Stretta

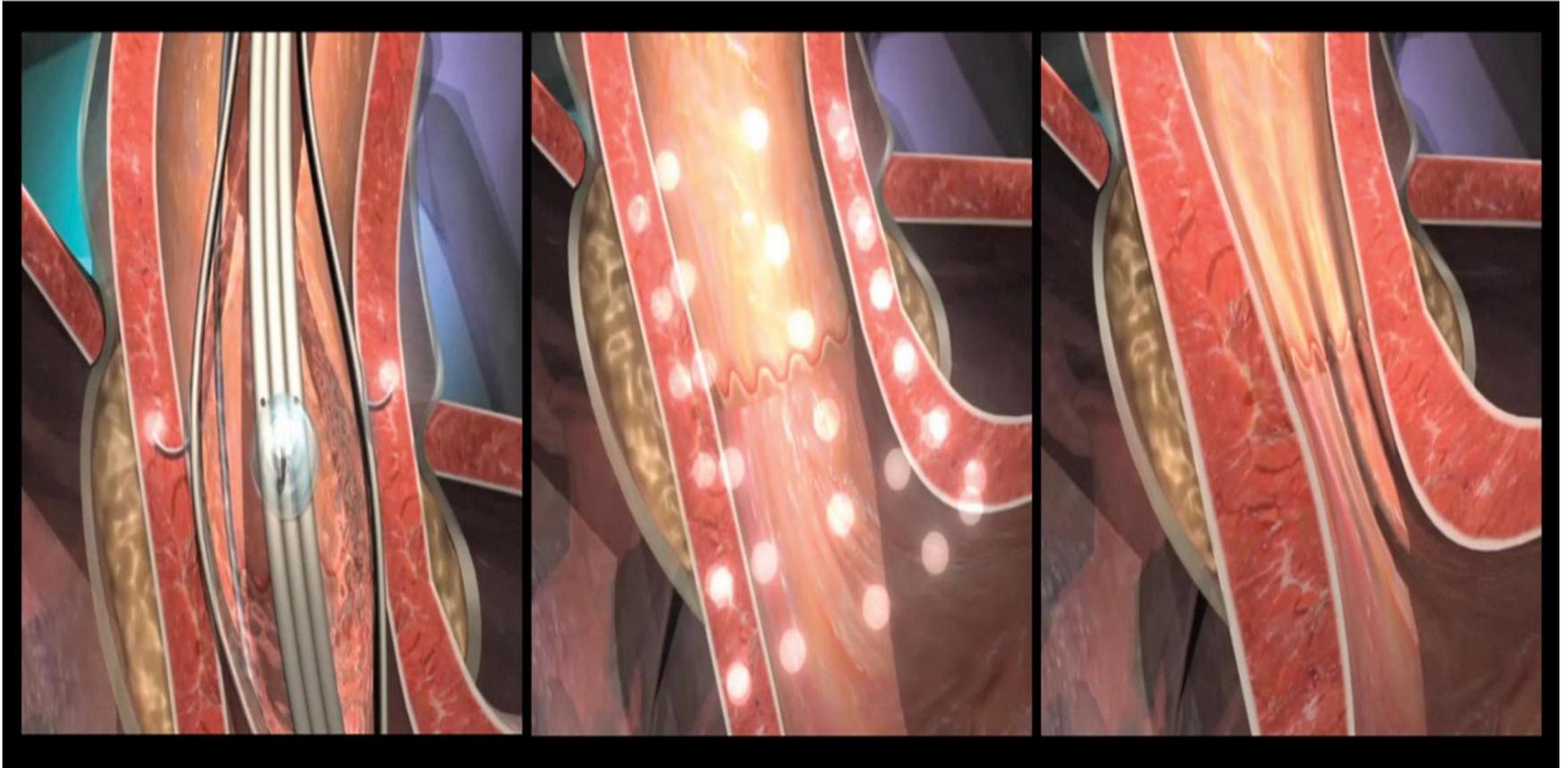


panier

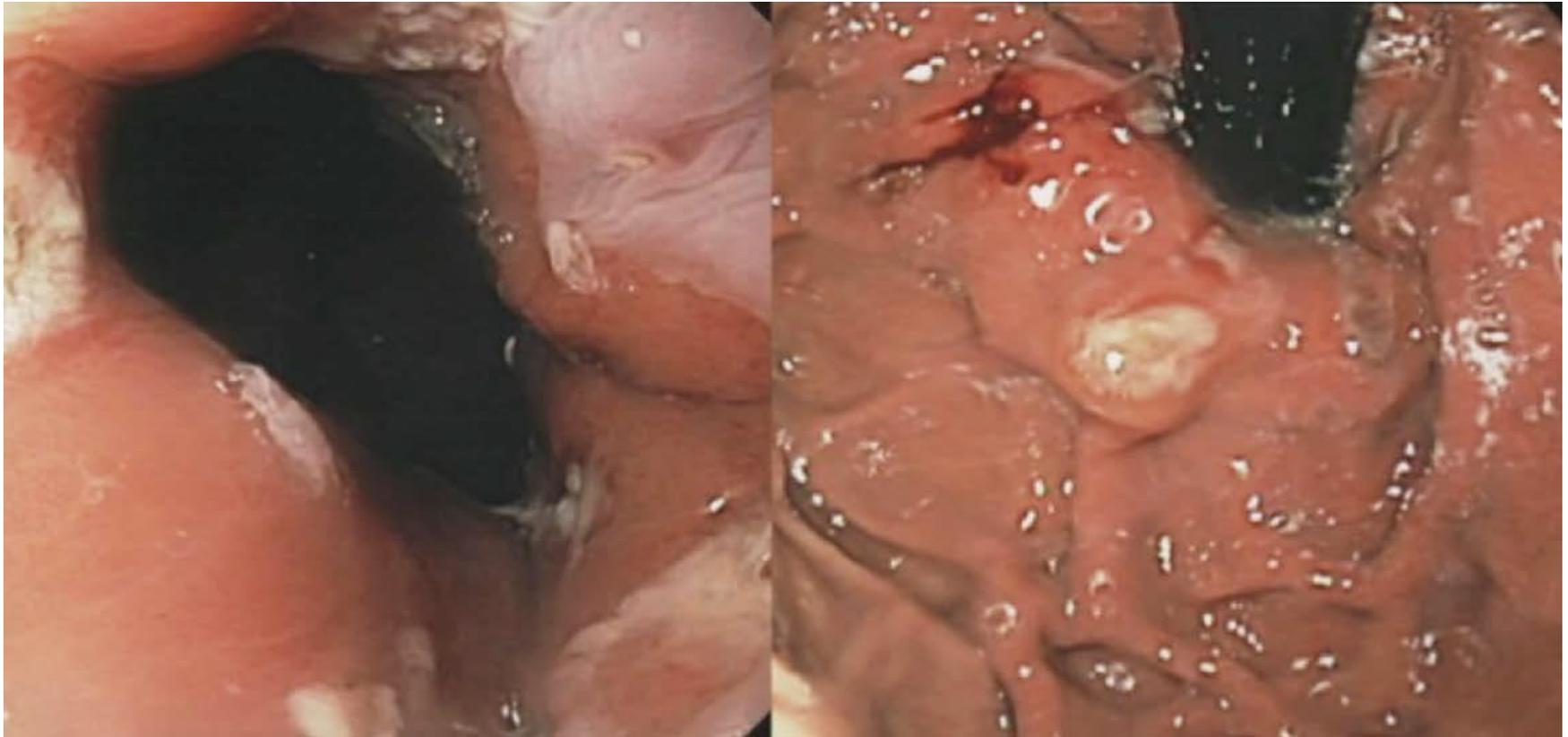
ballon

électrodes

Extrémité type bougie



série répétée tous les 0,5 cm vers l'intérieur, couvrant une zone de 2 cm au-dessus et à 0,5 cm en dessous de la jonction squamo-colonnaire.



World J Gastroenterol 2014; 20: 7730-8

Indications de Stretta:

- une œsophagite grade A ou B
- PHmétrie anormale: score de DeMeester $\geq 14,7$ avec corrélation des symptômes $\geq 50\%$ et / ou épisodes de reflux > 73 sur 24 heures;
- Absence de HH ou HH < 2 cm
- Absence d'œsophage de Barrett
- Absence de pression très basse du SIO (< 5 mmHg)

REVIEW

Systematic review and meta-analysis of controlled and prospective cohort efficacy studies of endoscopic radiofrequency for treatment of gastroesophageal reflux disease

Ronnie Fass¹ · Frederick Cahn² · Dennis J. Scotti³ · David A. Gregory⁴

Received: 9 October 2016 / Accepted: 20 January 2017 / Published online: 23 February 2017
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Abstract

Background The endoscopic radiofrequency procedure (Stretta) has been used for more than a decade to treat patients with gastroesophageal reflux disease (GERD). However, the efficacy of the procedure in improving objective and subjective clinical endpoints needs to be further established.

36.7] months. The pooled results showed that the Stretta reduced (improved) the health-related quality of life score by -14.6 [-16.48 , -12.73] ($P < 0.001$). Stretta also reduced (improved) the pooled heartburn standardized score by -1.53 [-1.97 , -1.09] ($P < 0.001$). After Stretta treatment, only 49% of the patients using proton pump inhibitors (PPIs) at baseline required PPIs at follow-up.

Méta-analyse 2017

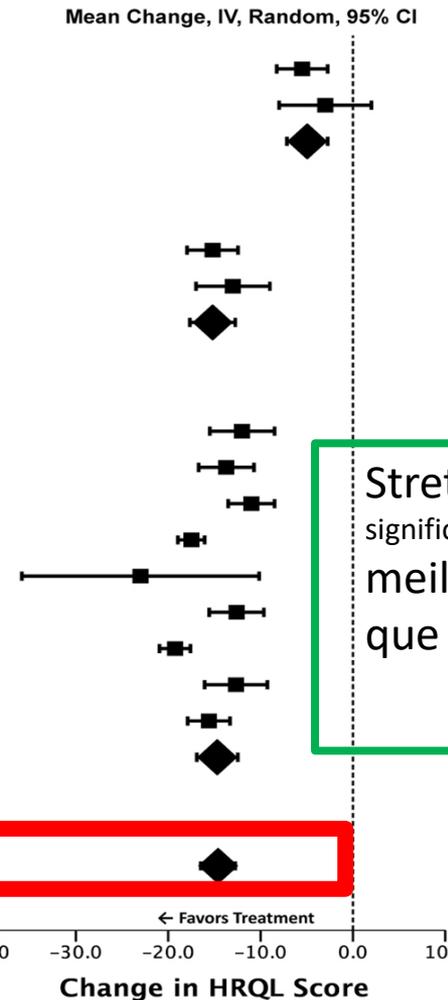
- But: Déterminer l'efficacité de Stretta
- 28 études, 2468 patients
- Essais contrôlés randomisés (n=4)
- Cohortes prospectives (n=23)
- Registre prospectif (n=1)

Critères de jugement

- Questionnaire Qualité de vie
- Score de pyrosis
- Utilisation des IPP
- Œsophagite érosive
- Exposition acide de l'œsophage
- Pression basale du SIO

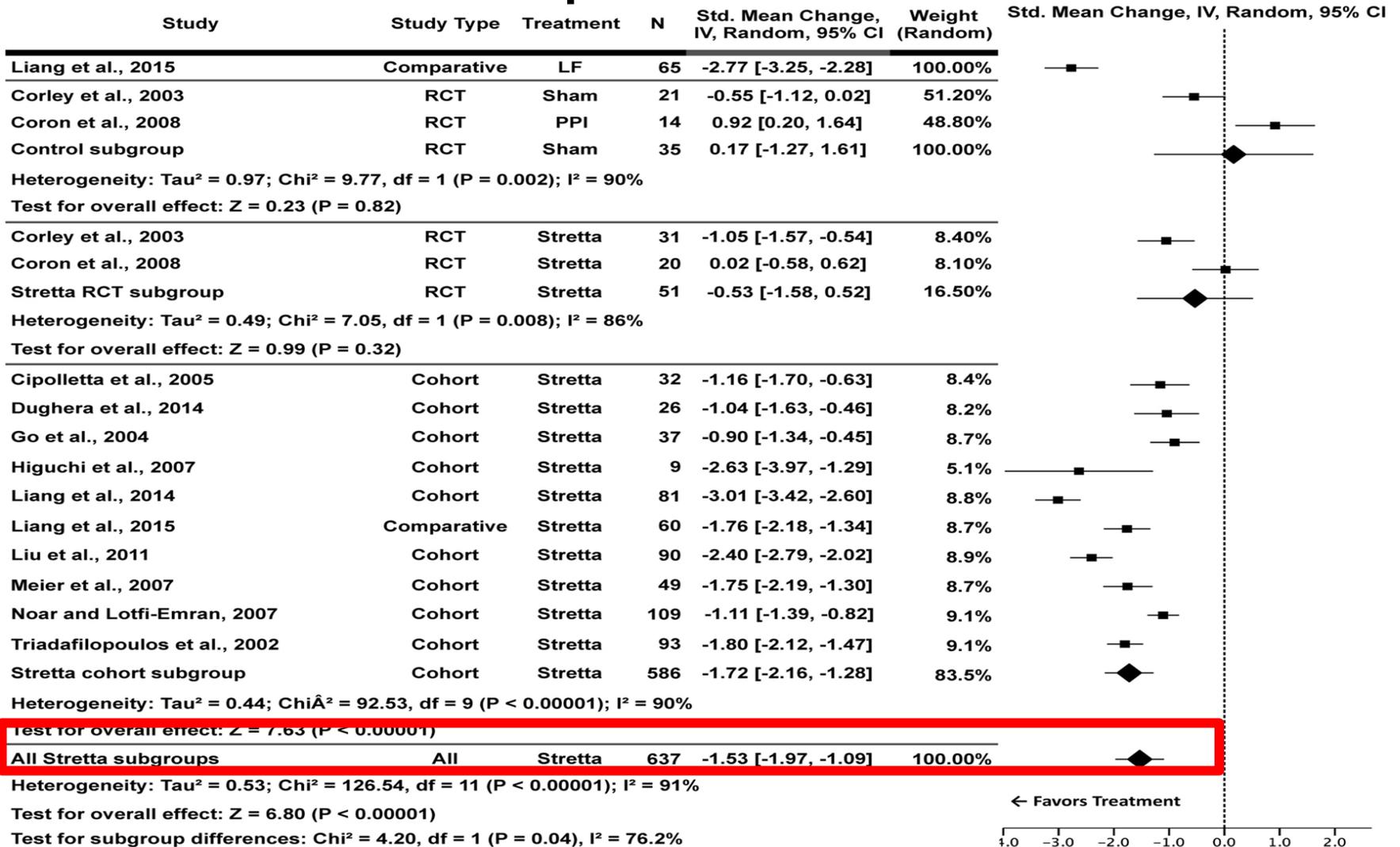
HRQL: 2 RCT, 9 cohortes, 507 patients

Study	Study Type	Treatment	N	SE	Mean Change, IV, Random, 95% CI	Weight (Random)
Aziz et al. 2010	RCT	Sham	12	1.27	-5.50 [-7.99, -3.01]	78.1%
Corley et al. 2003	RCT	Sham	21	2.40	-3.00 [-7.70, 1.70]	21.9%
Sham Subgroup	RCT	Sham	33		-4.95 [-7.15, -2.75]	100.00%
Heterogeneity: Tau ² = 0.00; Chi ² = 0.85, df = 1 (P = 0.36); I ² = 0%						
Test for overall effect: Z = 4.41 (P < 0.0001)						
Aziz, El-Khayat et al., 2010	RCT	Stretta	12	1.26	-15.20 [-17.67, -12.73]	10.1%
Corley et al. 2003	RCT	Stretta	31	1.96	-13.00 [-16.84, -9.16]	8.1%
Stretta RCT Subgroup	RCT	Stretta	43		-14.56 [-16.63, -12.48]	18.1%
Heterogeneity: Tau ² = 0.00; Chi ² = 0.89, df = 1 (P = 0.35); I ² = 0%						
Test for overall effect: Z = 13.73 (P < 0.00001)						
Cipollatta et al. 2005	Cohort	Stretta	32	1.72	-12.00 [-15.37, -8.63]	8.7%
DiBaise et al. 2002	Cohort	Stretta	18	1.43	-13.71 [-16.50, -10.92]	9.6%
Dughera et al. 2014	Cohort	Stretta	26	1.22	-11.00 [-13.38, -8.62]	10.2%
Liu et al. 2011	Cohort	Stretta	90	0.73	-17.50 [-18.93, -16.07]	11.4%
Mansell 2001	Cohort	Stretta	29	6.29	-23.00 [-35.32, -10.68]	1.9%
Meier et al. 2007	Cohort	Stretta	32	1.45	-12.60 [-15.44, -9.76]	9.5%
Noar et al. 2014	Cohort	Stretta	99	0.85	-19.26 [-20.92, -17.60]	11.1%
Tam et al. 2003	Cohort	Stretta	20	1.63	-12.67 [-15.86, -9.48]	9.0%
Triadafilopoulos et al. 2002	Cohort	Stretta	118	1.16	-15.60 [-17.87, -13.33]	10.3%
Stretta Cohort Subgroup	Cohort	Stretta	464		-14.69 [-16.90, -12.47]	81.9%
Heterogeneity: Tau ² = 8.84; Chi ² = 54.66, df = 8 (P < 0.00001); I ² = 85%						
Test for overall effect: Z = 15.28 (P < 0.00001)						
Test for subgroup differences: Chi ² = 0.01, df = 1 (P = 0.93), I ² = 0%						
All Stretta Subgroups	All	Stretta	507		-14.60 [-16.48, -12.73]	100.00%



Stretta est significativement meilleure que Sham

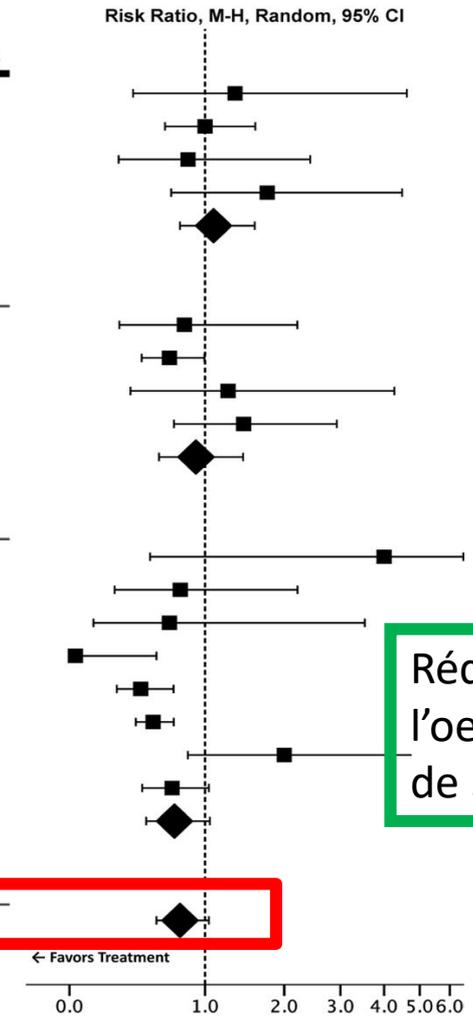
pyrosis score: 2 RCT, 11 cohorts, 1149 patients



Oesophagite, 12 études, 444 patients

A

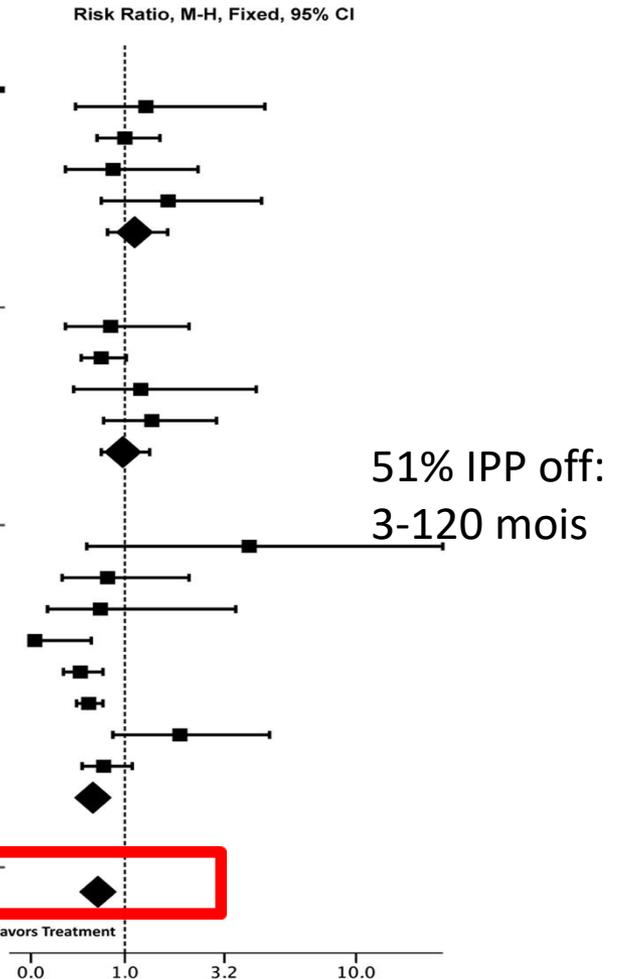
Study	Study Type	Treatment	Baseline		Follow-up		Risk Ratio, M-H, Random, 95% CI	Weight (Random)
			N	Esophagitis	N	Esophagitis		
Arts et al., 2012	RCT	Sham	11	3	11	4	1.33 [0.39, 4.62]	8.8%
Aziz et al., 2010	RCT	Sham	12	9	12	9	1.00 [0.63, 1.59]	63.9%
Corley et al., 2003	RCT	Sham	29	6	29	5	0.83 [0.29, 2.43]	11.9%
Coron et al., 2008	RCT	PPI	20	5	16	7	1.75 [0.68, 4.48]	15.4%
Control Subgroup	RCT	Sham	72	23	68	25	1.09 [0.76, 1.58]	100.0%
Heterogeneity: Tau ² = 0.00; Chi ² = 1.52, df = 3 (P = 0.68); I ² = 0%								
Test for overall effect: Z = 0.48 (P = 0.63)								
Arts et al., 2012	RCT	Stretta	11	5	11	4	0.80 [0.29, 2.21]	6.4%
Aziz et al., 2010	RCT	Stretta	12	12	12	8	0.68 [0.45, 1.02]	14.7%
Corley et al., 2003	RCT	Stretta	35	4	35	5	1.25 [0.37, 4.27]	4.8%
Coron et al., 2008	RCT	Stretta	23	8	20	10	1.44 [0.71, 2.93]	9.7%
Stretta RCT Subgroup	RCT	Stretta	81	29	78	27	0.91 [0.58, 1.43]	35.6%
Heterogeneity: Tau ² = 0.07; Chi ² = 4.41, df = 3 (P = 0.22); I ² = 32%								
Test for overall effect: Z = 0.41 (P = 0.68)								
Arts et al., 2007	Cohort	Stretta	13	1	13	4	4.00 [0.51, 31.13]	2.1%
Cipolletta et al., 2005	Cohort	Stretta	32	8	21	4	0.76 [0.26, 2.21]	5.9%
DiBaise et al., 2002	Cohort	Stretta	18	3	18	2	0.67 [0.13, 3.53]	3.0%
Dughera et al., 2011	Cohort	Stretta	56	14	56	0	0.03 [0.00, 0.56]	1.2%
Liu et al., 2011	Cohort	Stretta	90	41	90	18	0.44 [0.27, 0.70]	13.6%
Reymunde and Santiago, 2007	Cohort	Stretta	72	60	72	32	0.53 [0.40, 0.70]	17.0%
Tam et al., 2003	Cohort	Stretta	20	5	20	10	2.00 [0.83, 4.81]	7.7%
Triadafilopoulos et al., 2002	Cohort	Stretta	118	35	118	25	0.71 [0.46, 1.11]	14.0%
Mean Stretta (Cohort)	Cohort	Stretta	419	167	408	95	0.69 [0.45, 1.04]	64.4%
Heterogeneity: Tau ² = 0.17; Chi ² = 17.78, df = 7 (P = 0.01); I ² = 61%								
Test for overall effect: Z = 1.73 (P = 0.08)								
Mean Stretta (All)	Total	Stretta	500	196	486	122	0.76 [0.56, 1.04]	100.0%
Heterogeneity: Tau ² = 0.13; Chi ² = 24.60, df = 11 (P = 0.01); I ² = 55%								
Test for overall effect: Z = 1.74 (P = 0.08)								
Test for subgroup differences: Chi ² = 0.81, df = 1 (P = 0.37), I ² = 0%								



Utilisation des IPP, 23 études, 1795 patients

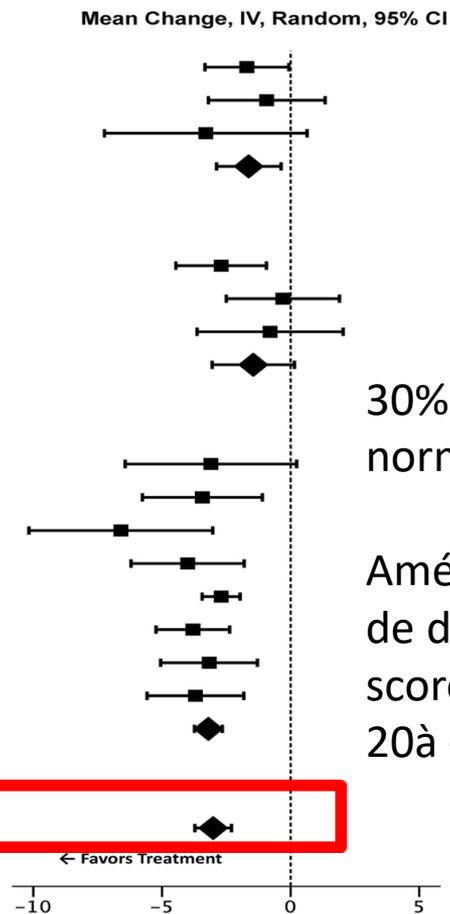
B

Study	Study Type	Treatment	Baseline		Follow-up		Risk Ratio, M-H, Fixed, 95% CI	Weight
			N	Esoph-agitis	N	Esoph-agitis		
Arts et al., 2012	RCT	Sham	11	3	11	4	1.33 [0.39, 4.62]	13.4%
Aziz et al., 2010	RCT	Sham	12	9	12	9	1.00 [0.63, 1.59]	40.1%
Corley et al., 2003	RCT	Sham	29	6	29	5	0.83 [0.29, 2.43]	26.7%
Coron et al., 2008	RCT	PPI	20	5	16	7	1.75 [0.68, 4.48]	19.8%
Control Subgroup	RCT	Sham	72	23	68	25	1.15 [0.76, 1.74]	100.0%
Heterogeneity: $\text{Chi}^2 = 1.52$, $\text{df} = 3$ ($P = 0.68$); $I^2 = 0\%$								
Test for overall effect: $Z = 0.65$ ($P = 0.52$)								
Arts et al., 2012	RCT	Stretta	11	5	11	4	0.80 [0.29, 2.21]	2.6%
Aziz et al., 2010	RCT	Stretta	12	12	12	8	0.68 [0.45, 1.02]	6.4%
Corley et al., 2003	RCT	Stretta	35	4	35	5	1.25 [0.37, 4.27]	2.1%
Coron et al., 2008	RCT	Stretta	23	8	20	10	1.44 [0.71, 2.93]	3.8%
Stretta RCT Subgroup	RCT	Stretta	81	29	78	27	0.97 [0.68, 1.40]	14.9%
Heterogeneity: $\text{Chi}^2 = 4.41$, $\text{df} = 3$ ($P = 0.22$); $I^2 = 32\%$								
Test for overall effect: $Z = 0.14$ ($P = 0.89$)								
Arts et al., 2007	Cohort	Stretta	13	1	13	4	4.00 [0.51, 31.13]	0.5%
Cipolletta et al., 2005	Cohort	Stretta	32	8	21	4	0.76 [0.26, 2.21]	3.3%
DiBaise et al., 2002	Cohort	Stretta	18	3	18	2	0.67 [0.13, 3.53]	1.5%
Dughera et al., 2011	Cohort	Stretta	56	14	56	0	0.03 [0.00, 0.56]	7.4%
Liu et al., 2011	Cohort	Stretta	90	41	90	18	0.44 [0.27, 0.70]	21.0%
Reymunde and Santiago, 2007	Cohort	Stretta	72	60	72	32	0.53 [0.40, 0.70]	30.8%
Tam et al., 2003	Cohort	Stretta	20	5	20	10	2.00 [0.83, 4.81]	2.6%
Triadafilopoulos et al., 2002	Cohort	Stretta	118	35	118	25	0.71 [0.46, 1.11]	18.0%
Mean Stretta (Cohort)	Cohort	Stretta	419	167	408	95	0.58 [0.47, 0.71]	85.1%
Heterogeneity: $\text{Chi}^2 = 17.78$, $\text{df} = 7$ ($P = 0.01$); $I^2 = 61\%$								
Mean Stretta (All)	Total	Stretta	500	196	486	122	0.64 [0.54, 0.76]	100.0%
Test for overall effect: $Z = 4.96$ ($P < 0.00001$)								
Test for subgroup differences: $\text{Chi}^2 = 5.90$, $\text{df} = 1$ ($P = 0.02$), $I^2 = 83.1\%$								

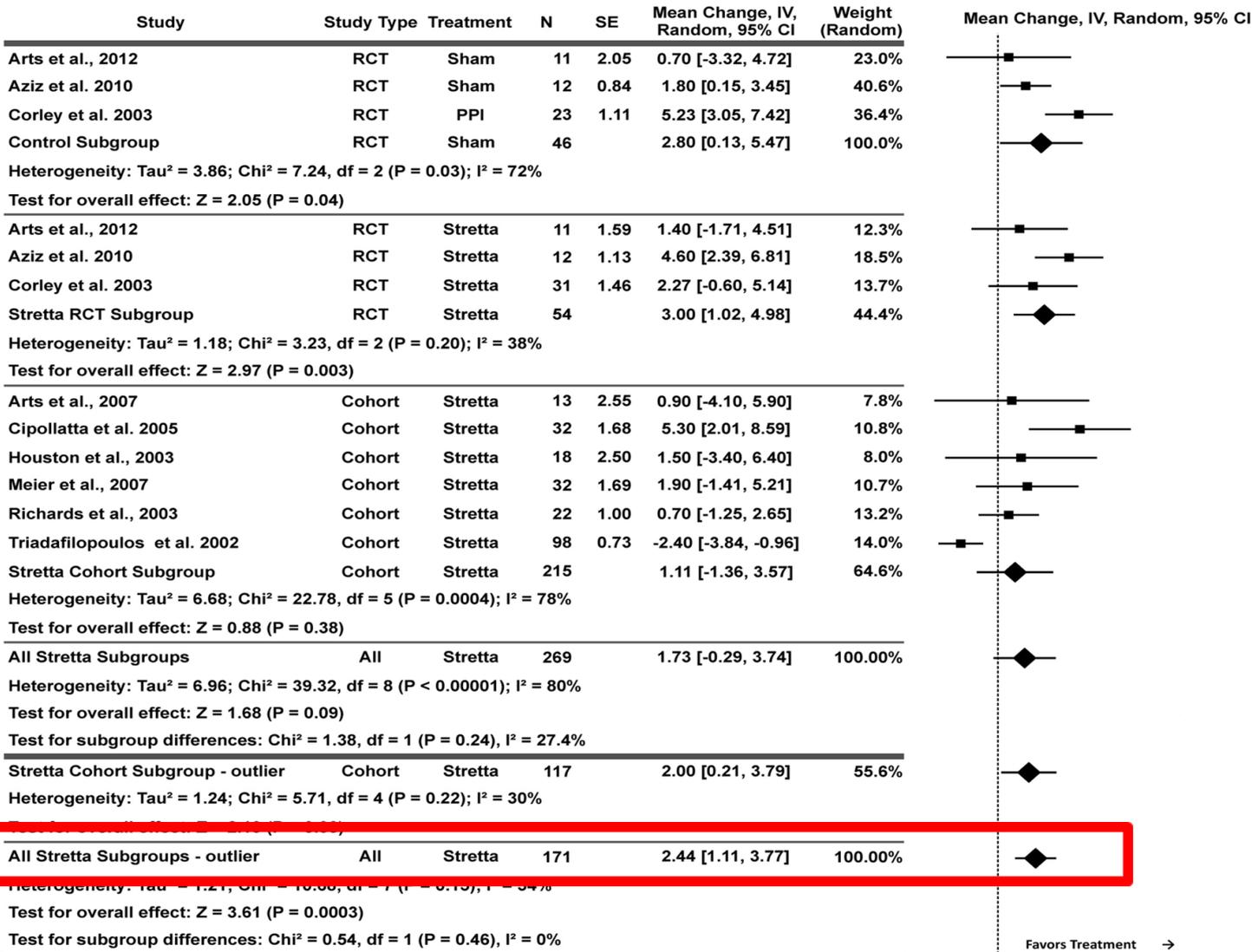


Exposition acide, 11 études, 364 patients

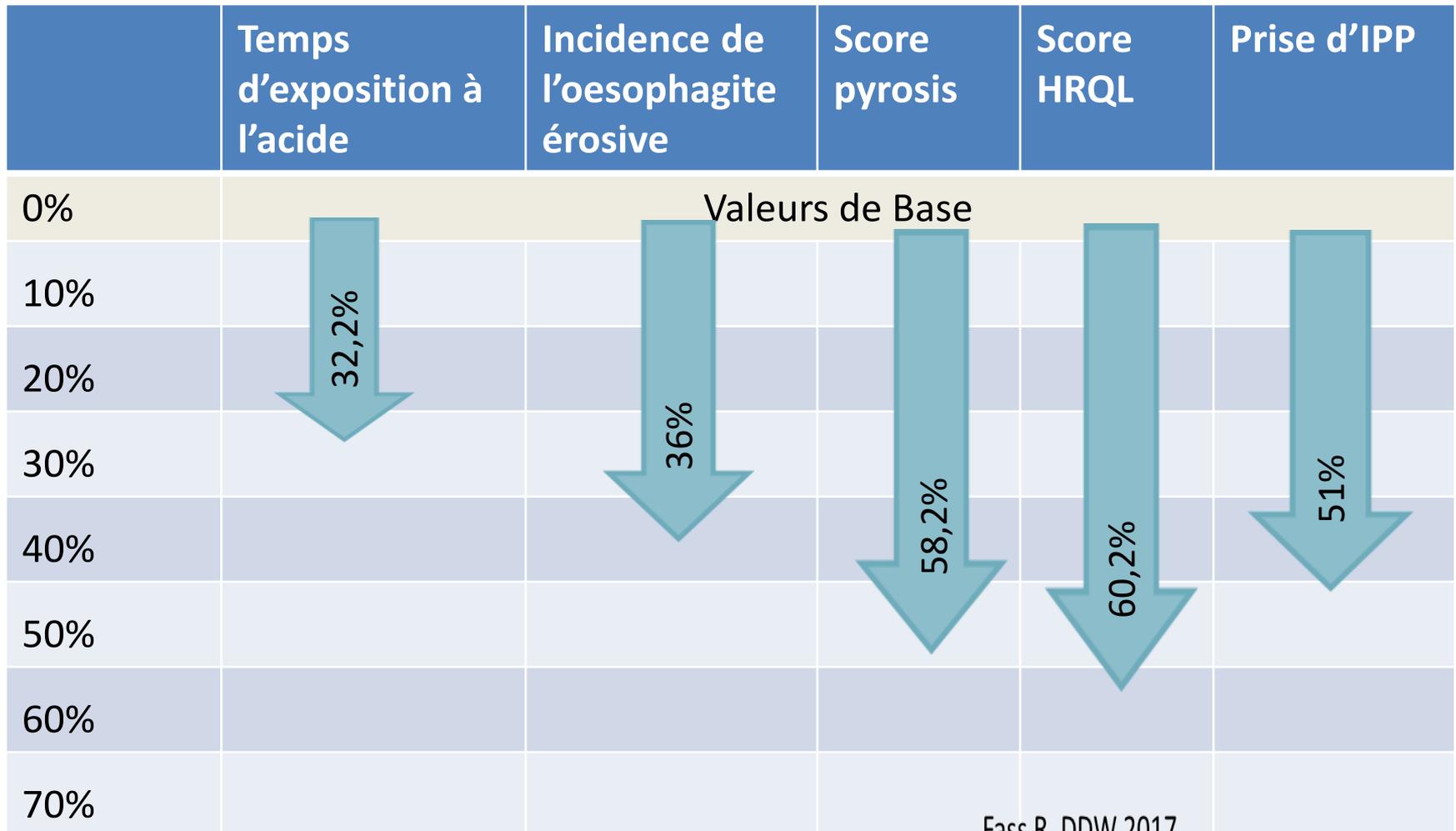
Study	Study Type	Treatment	N	SE	Mean Change, IV, Random, 95% CI	Weight (Random)
Aziz et al., 2010	RCT	Sham	12	0.83	-1.70 [-3.33, -0.07]	59.40%
Corley et al., 2003	RCT	Sham	25	1.16	-0.93 [-3.20, 1.34]	30.40%
Coron et al., 2008	RCT	PPI	16	2.01	-3.30 [-7.24, 0.64]	10.10%
Control Subgroup	RCT	Sham	53		-1.63 [-2.88, -0.37]	100.00%
Heterogeneity: Tau ² = 0.00; Chi ² = 1.06, df = 2 (P = 0.59); I ² = 0%						
Test for overall effect: Z = 2.54 (P = 0.01)						
Aziz et al., 2010	RCT	Stretta	12	0.90	-2.70 [-4.46, -0.94]	10.40%
Corley et al., 2003	RCT	Stretta	31	1.12	-0.30 [-2.50, 1.90]	7.70%
Coron et al., 2008	RCT	Stretta	20	1.45	-0.80 [-3.64, 2.04]	5.10%
Stretta RCT Subgroup	RCT	Stretta	63		-1.45 [-3.05, 0.15]	23.30%
Heterogeneity: Tau ² = 0.74; Chi ² = 3.14, df = 2 (P = 0.21); I ² = 36%						
Test for overall effect: Z = 1.78 (P = 0.08)						
Arts et al., 2007	Cohort	Stretta	13	1.70	-3.10 [-6.43, 0.23]	3.90%
Cipolletta et al., 2005	Cohort	Stretta	32	1.19	-3.43 [-5.76, -1.10]	7.00%
DiBaise et al., 2002	Cohort	Stretta	18	1.82	-6.60 [-10.17, -3.03]	3.50%
Houston et al., 2003	Cohort	Stretta	18	1.12	-4.00 [-6.20, -1.80]	7.70%
Lutfi et al., 2005	Cohort	Stretta	61	0.38	-2.70 [-3.44, -1.96]	22.10%
Richards et al., 2003	Cohort	Stretta	22	0.73	-3.80 [-5.23, -2.37]	13.40%
Tam et al., 2003	Cohort	Stretta	19	0.96	-3.17 [-5.05, -1.29]	9.60%
Triadafilopoulos et al., 2002	Cohort	Stretta	118	0.96	-3.70 [-5.58, -1.82]	9.60%
Stretta Cohort Subgroup	Cohort	Stretta	301		-3.20 [-3.74, -2.66]	76.70%
Heterogeneity: Tau ² = 0.00; Chi ² = 6.72, df = 7 (P = 0.46); I ² = 0%						
Test for overall effect: Z = 11.56 (P < 0.00001)						
All Stretta Subgroups	All	Stretta	364		-3.01 [-3.72, -2.30]	100.00%
Heterogeneity: Tau ² = 0.45; Chi ² = 15.39, df = 10 (P = 0.12); I ² = 35%						
Test for overall effect: Z = 8.30 (P < 0.00001)						
Test for subgroup differences: Chi ² = 4.11, df = 1 (P = 0.04), I ² = 75.7%						



Pression du SIO, 9 études, 269 patients



Améliorations ou Réductions significatives post Stretta



Effets secondaires

- Stretta: 0,93% (érosions, fièvre, douleurs thoraciques, dysphagie transitoire - Lacérations)
- Fundoplicature laparoscopique: 7,18% (emphysème sous-muqueux)

Radiofrequency energy delivery to the lower esophageal sphincter improves gastroesophageal reflux patient-reported outcomes in failed laparoscopic Nissen fundoplication cohort

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Abstract

Background Patients with uncontrollable gastroesophageal reflux disease (GERD) often undergo laparoscopic Nissen fundoplication (LNF); however, long-term there are often recurring symptoms and need for continuous medication use. Refractory LNF patients may receive radiofrequency energy delivery to the lower esophageal sphincter (Stretta) to ameliorate symptoms and medication requirements. The aim was to assess and compare long-term patient-reported outcomes of Stretta in refractory patients with and without previous LNF.

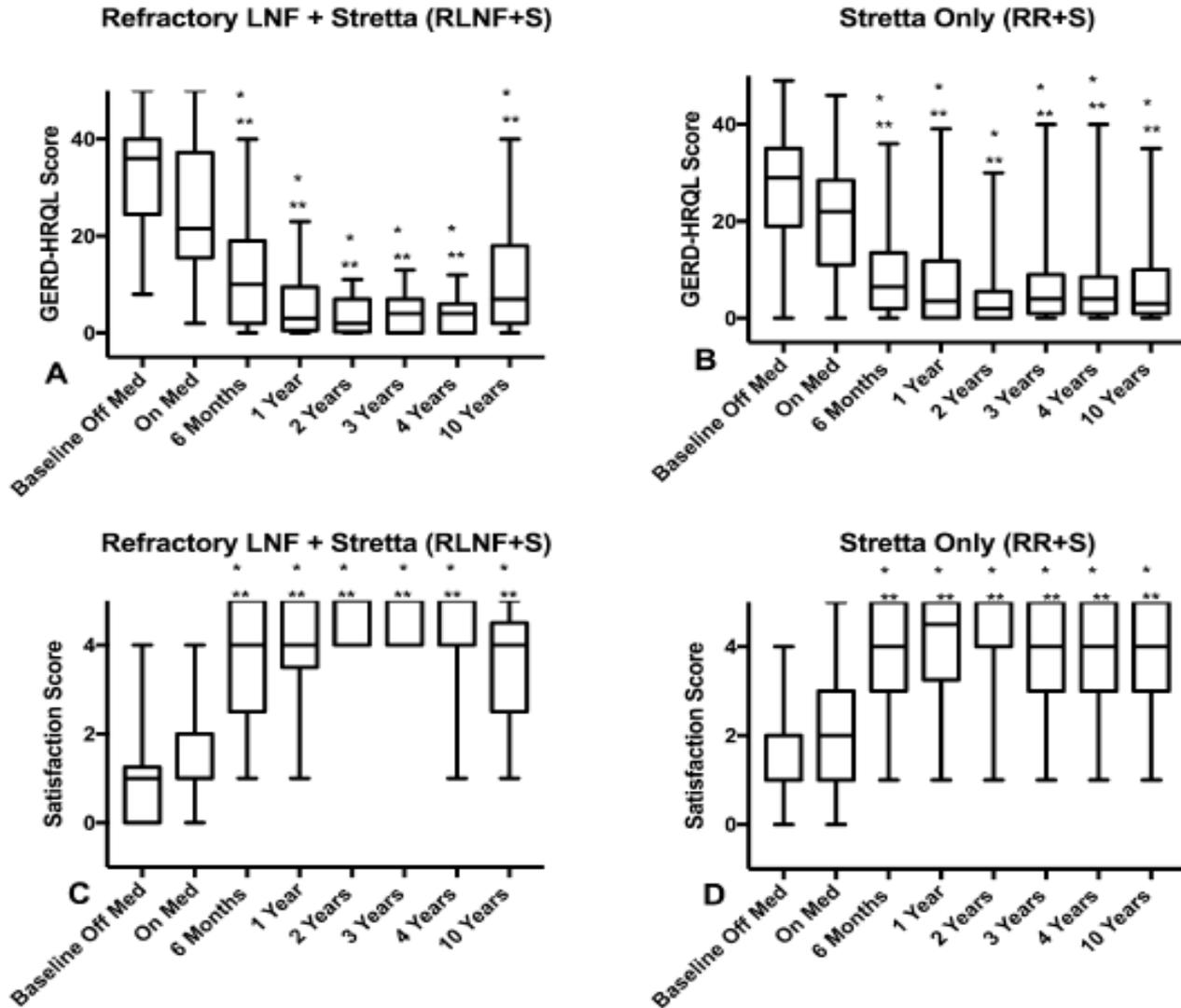
Methods We prospectively assessed and compared patient-reported outcomes in 18 refractory LNF patients and 81 standard refractory GERD patients that all underwent Stretta during 10-year follow-up. Patient-reported outcomes measured were GERD-HRQL (health-related quality of life), patient satisfaction scores, and daily medication requirements.

Results The refractory LNF subset demonstrated median improvements in GERD-HRQL, satisfaction, and

medication use at all follow-up time points ≥ 6 months to 10 years, which was significant from a baseline of both on- and off-medications ($p < 0.05$). Specifically at 10 years, median GERD-HRQL decreased from 36 to 7 ($p < 0.001$), satisfaction increased from 1 to 4 ($p < 0.001$), and medication score decreased from 7 to 6 ($p = 0.040$). Nine patients decreased medication use by half at 10 years. No significant differences existed between refractory LNF and standard refractory GERD subsets at any follow-up time point ≥ 6 months to 10 years ($p > 0.05$) after Stretta. At 10 years, no significant differences were noted between refractory LNF and standard Stretta subsets regarding medication use ($p = 0.088$), patient satisfaction ($p = 0.573$), and GERD-HRQL ($p = 0.075$). Stretta procedures were completed without difficulty or significant intraoperative or long-term adverse events.

Conclusion Within a small cohort of refractory LNF patients, Stretta resulted in sustained improvement over 10 years with equivalent outcomes to non-LNF standard Stretta patients. Refractory LNF patients are a subpopulation that may be safely, effectively, and robustly aided by Stretta with fewer complications compared to redo of Nissen or chronic medication use.

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LES SUTURES ENDOSCOPIQUES

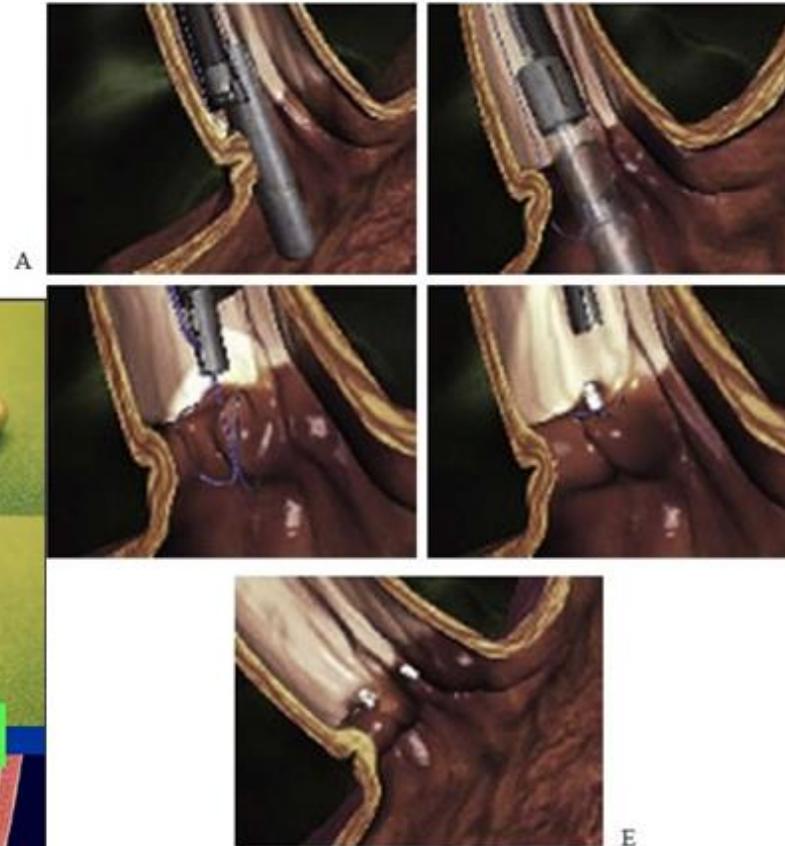
Les sutures endoscopiques

- Reproduisent à minima le traitement chirurgical
- Création d'une valve muqueuse par des points réalisés à partir de la lumière digestive
- Plusieurs compagnies +++
- EndoCinch*
- NDO chirurgical*
- Muse* EsophyX*



Systemes de suture ou plicature

Endocinch



- A- La paroi cardiaque est aspirée dans la fenêtre prévue à cet effet
- B- Passage du fil de suture
- C- suture aboutissant à la plicature de la paroi
- D- Serrage du noeud
- E- 2-4 sutures nécessaires

Systèmes de suture ou plicature

ESD

Cook Endocopic Suture Device ESD™

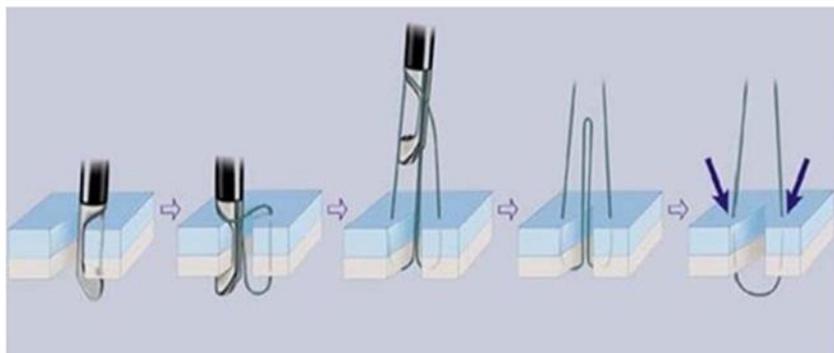
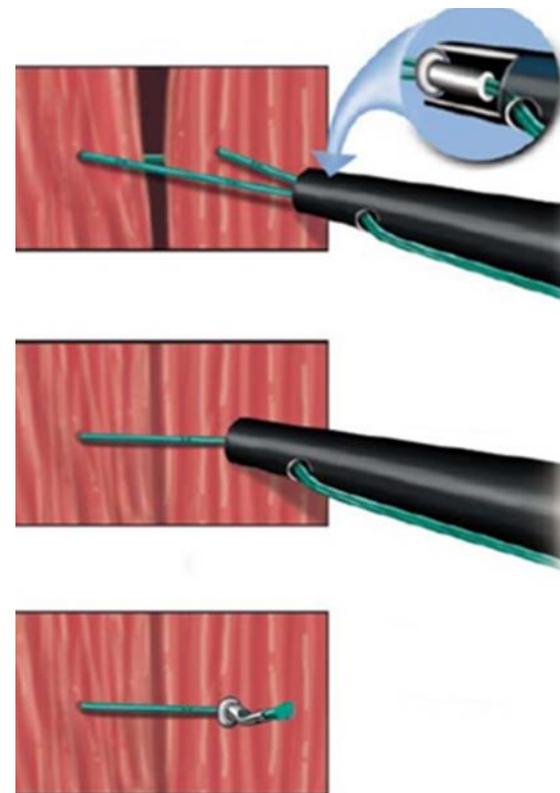
SR•5™ Device Operation



With a (single) squeeze of the lever the first needle passes through the tissue.



The needle automatically captures the suture and pulls it back through the tissue.



Systemes de suture ou plicature

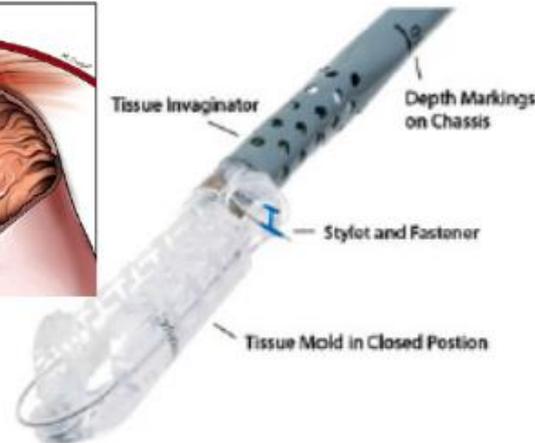
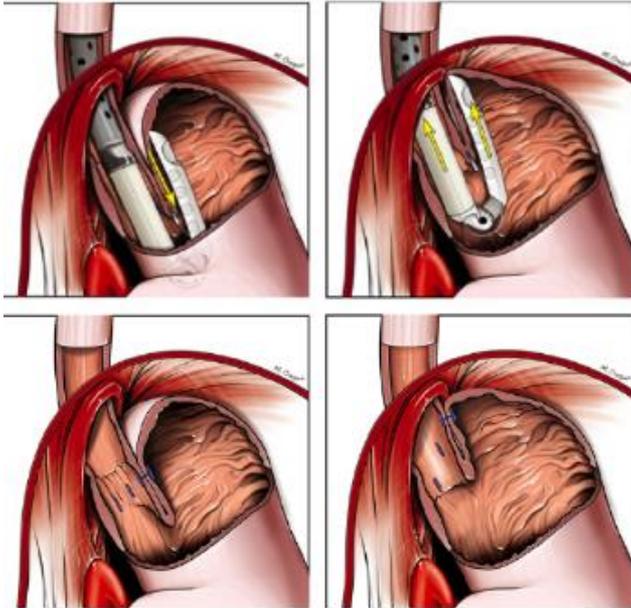
Plicator

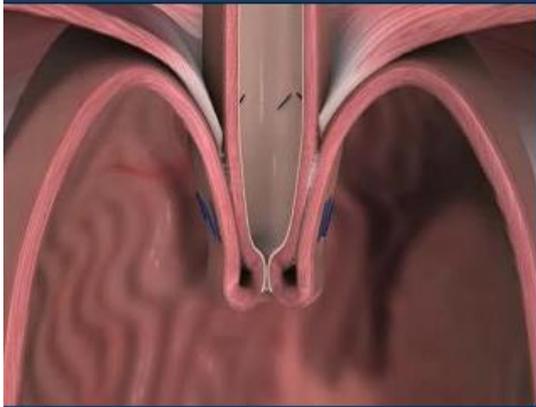
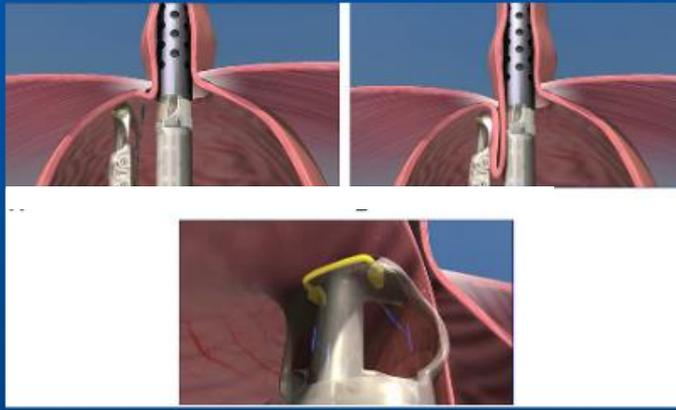


- A 12 mois, 68% des patients ont arrêté ou réduit l'utilisation des IPP
- 30%, amélioration du score Phmétric à 6 mois

Systemes de suture ou plicature

Esophyx

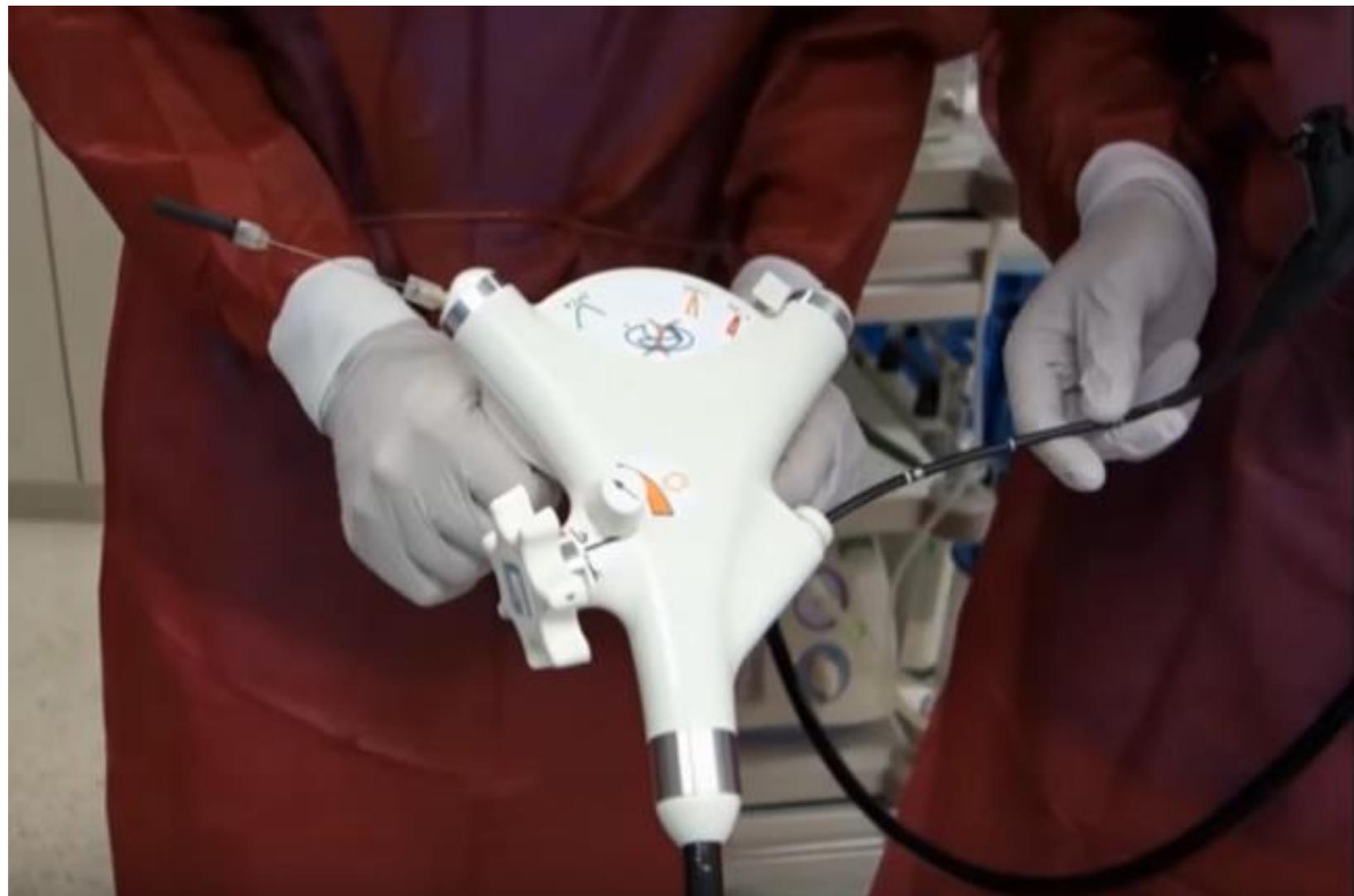




GERD X system

- Combinaison d'un ttt endoscopique et technologie microhydrolique





Chirurgie vs Endoscopie ?

Endoscopic and laparoscopic treatment of gastroesophageal reflux.

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Abstract

Gastroesophageal reflux is extremely common in Western countries. For selected patients, there is an established role for the surgical treatment of reflux, and possibly an emerging role for endoscopic antireflux procedures. Randomized trials have compared medical versus surgical management, laparoscopic versus open surgery and partial versus total funduplications. However, the evidence base for endoscopic procedures is limited to some small sham-controlled studies, and cohort studies with short-term follow-up. Laparoscopic fundoplication has been shown to be an effective antireflux operation. It facilitates quicker convalescence and is associated with fewer complications, but has a similar longer term outcome compared with open antireflux surgery. In most randomized trials, antireflux surgery achieves at least as good control of reflux as medical therapy, and these studies support a wider application of surgery for the treatment of moderate-to-severe reflux. Laparoscopic partial fundoplication is an **effective surgical procedure with fewer side effects**, and it may achieve high rates of patient satisfaction at late follow-up. Many of the early endoscopic antireflux procedures have failed to achieve effective reflux control, and they have been withdrawn from the market. Newer procedures have the potential to fashion a surgical fundoplication. However, at present there is **insufficient evidence to establish the safety and efficacy of endoscopic procedures** for the treatment of gastroesophageal reflux, and no endoscopic procedure has achieved equivalent reflux control to that achieved by surgical fundoplication.

The efficacy of the different endoscopic treatments versus sham, pharmacologic or surgical methods for chronic gastroesophageal reflux disease: a systematic review and meta-analysis

Martin Andrés CORONEL, Wanderley Marques BERNARDO, Diogo Turiani Hourneaux de MOURA, Eduardo Turiani Hourneaux de MOURA, Igor Braga RIBEIRO and Eduardo Guimarães Hourneaux de MOURA

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ABSTRACT – Background – Endoscopic antireflux treatments for gastroesophageal reflux disease (GERD) are still evolving, and most of the published studies address symptom relief in the short-term. **Objective** – We aimed to perform a systematic review and meta-analysis focused on evaluating the efficacy of the different endoscopic procedures. **Methods** – Search was restricted to randomized controlled trials (RCTs) on MedLine, Cochrane, Scielo, and EMBASE for patients with chronic GERD (>6 months), over 18 years old and available follow up of at least 3 months. The main outcome was to evaluate the efficacy of the different endoscopic treatments compared to sham, pharmacological or surgical treatment. Efficacy was measured by different subjective and objective outcomes. **Results** – We analyzed data from 16 RCT, totaling 1085 patients. The efficacy of endoscopic treatments compared to sham and proton pump inhibitors (PPIs) treatment showed a significant difference up to 6 months in favor of endoscopy with no heterogeneity ($P < 0.00001$) ($I^2: 0\%$). The subgroup analysis showed a statistically significant difference up to 6 months in favor of endoscopy: endoscopy vs PPI ($P < 0.00001$) ($I^2: 39\%$). Endoscopy vs sham ($P < 0.00001$) ($I^2: 0\%$). Most subjective and objective outcomes were statistically significant in favor of endoscopy up to 6 and 12 months follow up. **Conclusion** – This systematic review and meta-analysis shows a good short-term efficacy in favor of endoscopic procedures when comparing them to a sham and pharmacological or surgical treatment. Data on long-term follow up is lacking and this should be explored in future studies.

HEADINGS – Gastroesophageal reflux, therapy. Gastrointestinal endoscopy. Follow-Up Studies. Review.

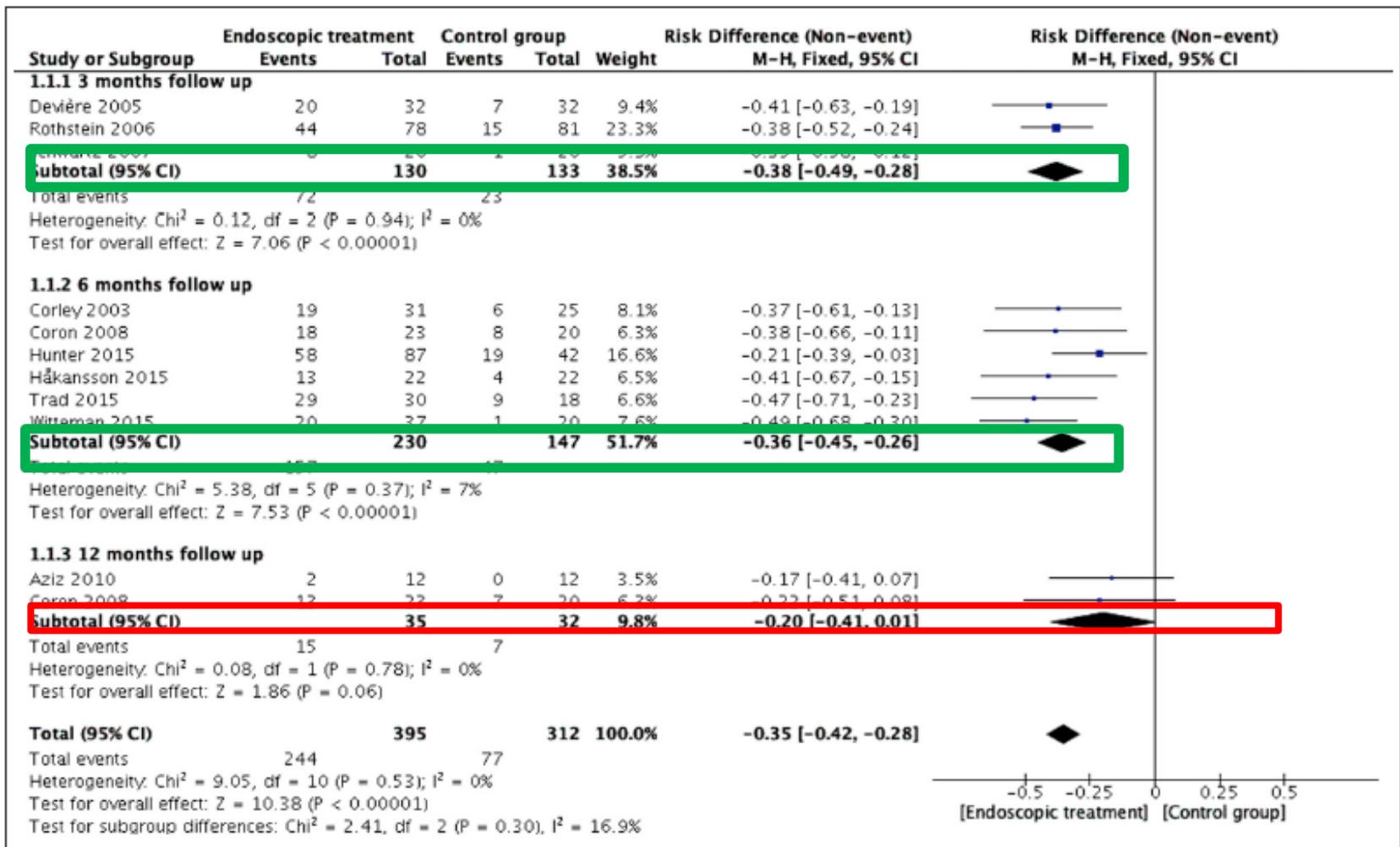


FIGURE 3. Efficacy of endoscopic treatments versus sham and PPI.

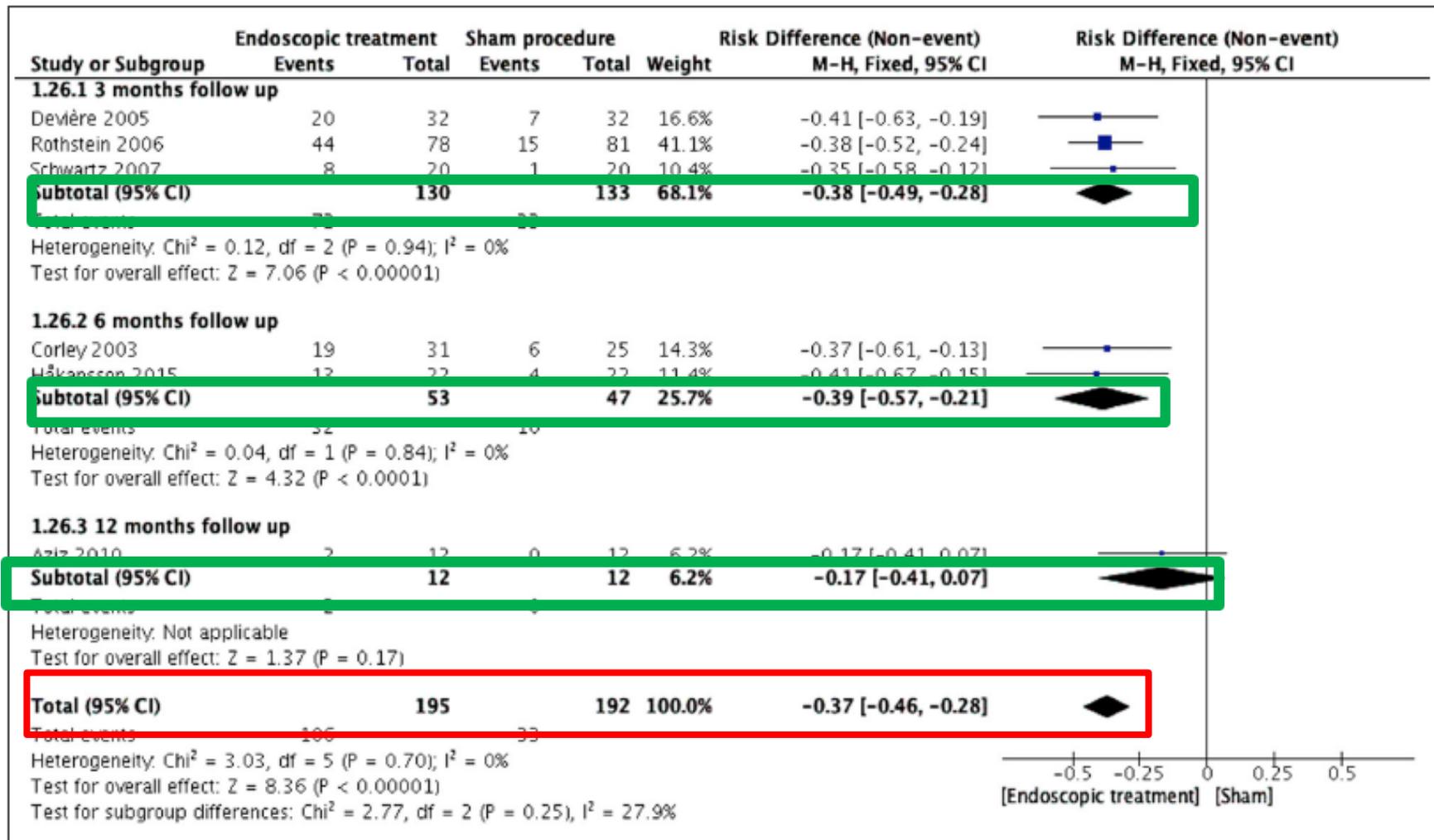
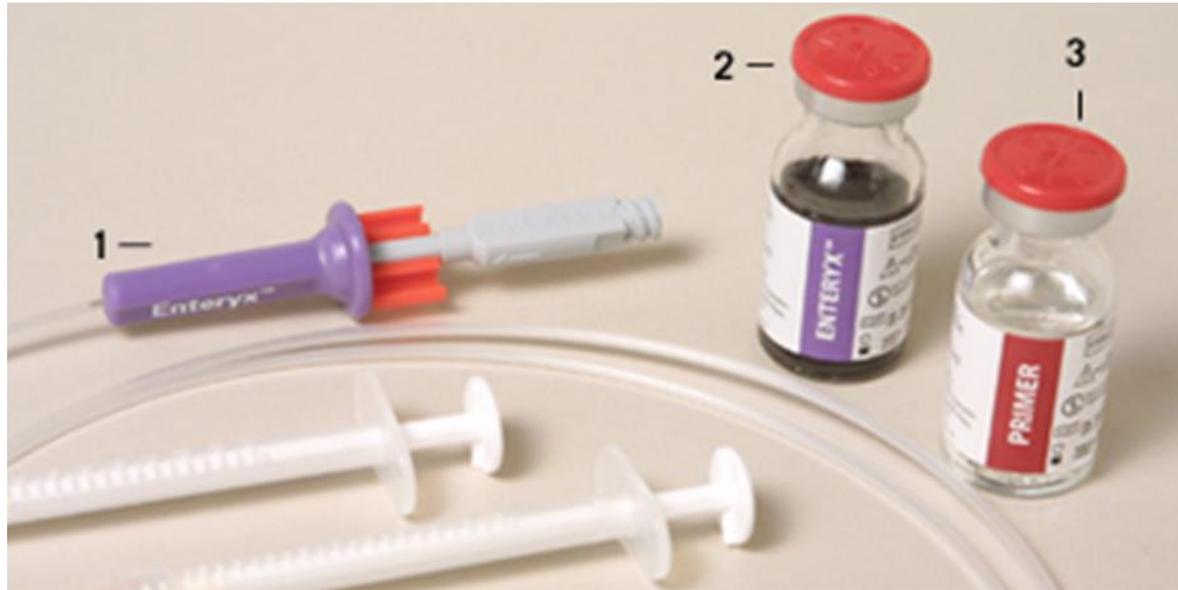


FIGURE 5. Efficacy of endoscopic treatment vs sham procedure.

Enteryx

Ozawa et al



FDA Preliminary Public Health Notification*: Recall of Boston Scientific ENTERYX[®] Procedure Kits and ENTERYX[®] Injector Single Packs for Treatment of Gastroesophageal Reflux Disease (GERD)

October 14, 2005

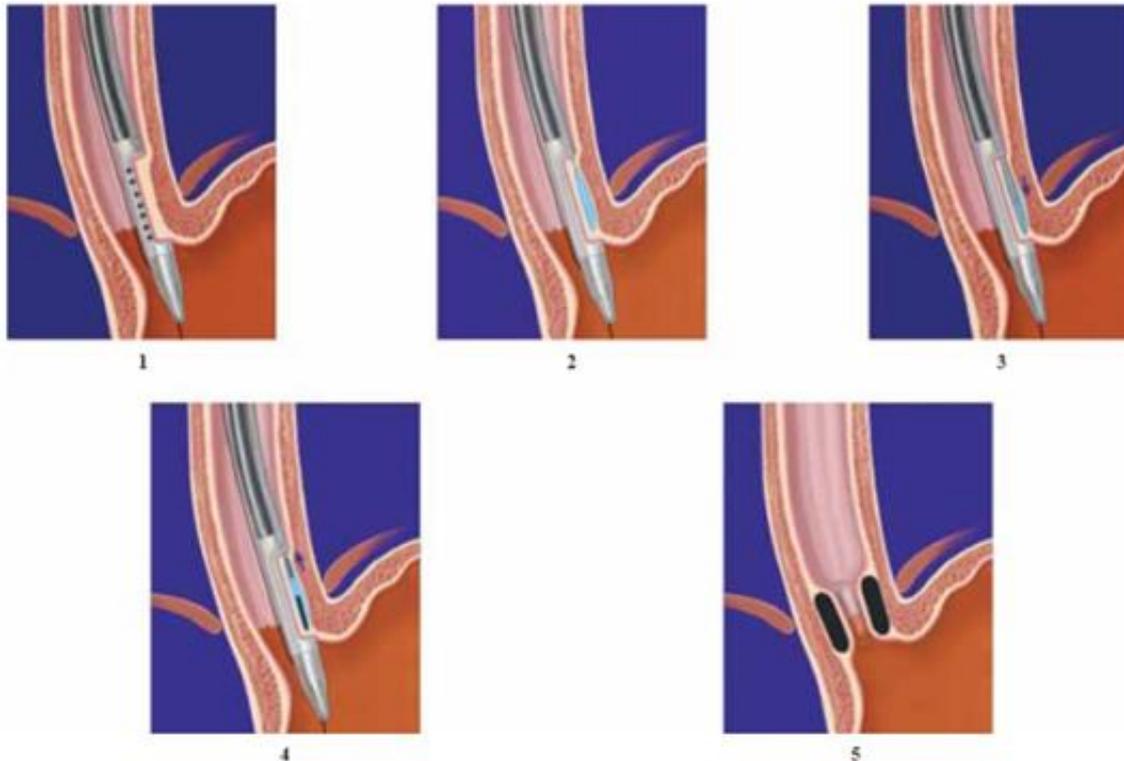
Dear Health care practitioner:

This is to let you know about serious adverse events, including death, occurring in patients treated with Boston Scientific's ENTERYX[®] for gastroesophageal reflux disease (GERD), and to provide recommendations on avoiding future occurrences.

On September 23, 2005, Boston Scientific Corporation issued a recall of ALL ENTERYX[®] Procedure Kits and ENTERYX[®] Injector Single Packs from commercial distribution. ***Physicians should stop injecting ENTERYX[®] immediately and follow the manufacturer's procedures for returning unused product.***

Injections de matériel synthétique inerte

Gatekeeper



Procédure Gatekeeper

- 1- Aspiration de la paroi oesophagienne
- 2- Injection de substance saline dans la sous-muqueuse
- 3- Création d'une poche dans la sous-muqueuse
- 4- Implantation de la prothèse HYPAN
- 5- Vue après l'implantation

Injections de matériel synthétique inerte

Gatekeeper

Surg Endosc. 2010 Mar 3. [Epub ahead of print]

Prospective randomized controlled trial of an injectable esophageal prosthesis versus a sham procedure for endoscopic treatment of gastroesophageal reflux disease.

Fockens P, Cohen L, Edmundowicz SA, Binmoeller K, Rothstein RI, Smith D, Lin E, Nickl N, Overholt B, Kahrilas PJ, Vakil N, Abdel Aziz Hassan AM, Lehman GA.

Academic Medical Center, University of Amsterdam, P.O. Box 22700, 1100 DE, Amsterdam, the Netherlands.

Abstract

BACKGROUND: This study aimed to assess whether endoscopic implantation of an injectable esophageal prosthesis, the Gatekeeper Reflux Repair System (GK), is a safe and effective therapy for controlling gastroesophageal reflux disease (GERD). **METHODS:** A prospective, randomized, sham-controlled, single-blinded, international multicenter study planned final enrollment of 204 patients in three groups: up to 60 lead-in, 96 GK, and 48 sham patients. The sham patients were allowed to cross over to the GK treatment arm or exit the study at 6 months. The primary end points were (1) reduction in serious device- and procedure-related adverse device effects compared with a surgical composite complication rate and (2) reduction in heartburn symptoms 6 months after the GK procedure compared with the sham procedure. The secondary end point was improved esophageal pH (total time pH was <4) 6 months after the GK procedure compared with baseline. **RESULTS:** A planned interim analysis was performed after 143 patients were enrolled (25 lead-in, 75 GK, and 43 sham patients), and the GK study was terminated early due to lack of compelling efficacy data. Four reported serious adverse events had occurred (2 perforations, 1 pulmonary infiltrate related to a perforation, and 1 severe chest pain) at termination of the study with no mortality or long-term sequelae. Heartburn symptoms had improved significantly at 6 months compared with baseline in the GK group ($p < 0.0001$) and the sham group ($p < 0.0001$), but no significant between-group difference in improvement was observed ($p = 0.146$). Esophageal acid exposure had improved significantly at 6 months compared with baseline in the GK group ($p = 0.021$) and the sham group ($p = 0.003$), but no significant between-group difference in improvement was observed ($p = 0.27$). **CONCLUSIONS:** The GK procedure was associated with some serious but infrequent complications. No statistically significant difference in outcomes was observed between the treatment and control groups at 6 months compared with baseline.

CONCLUSION

