

Technological Improvements for the Treatment of Obstructed Defecation Syndrome

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Abstract. *Background/Aim:* Standard stapled transanal rectal resection (STARR) with two PPH-01™ poses some questions regarding the completeness of prolapse resection in patients with obstructed defecation syndrome (ODS) since 20% to 30% of patients have persistent rectocele or rectal intussusception that may impair the physiological recovery of rectal sensitivity. New high-volume (HV) devices, such as CPH34 HV™ and CPH36 SMS™, allow for wider prolapsectomy to be performed and we herein assessed the possibility and safety of a STARR mono-stapler. *Materials and Methods:* On May 30th-31st 2011, 13 pigs were selected to undergo standard STARR with two PPH-01™ (n=2) or STARR mono-stapler with one CPH34 HV™ (n=11) at the Experimental Center of Vila do Conde (Portugal); another set of 13 pigs was selected on January 14th-17th 2014 to undergo standard STARR (n=2) or STARR mono-stapler by means of one CPH36 SMS™ (n=11). The length, height, square surface, and volume of resected specimens were intra-operatively assessed. Pigs were monitored for three days before undergoing transrectal sonography and autopsy to check for locoregional complications. *Results:* CPH36 SMS™ STARR mono-stapler achieved 57% higher volume of prolapsectomy compared to Standard STARR (p=0.008); moreover, surface measures of the specimens of CPH36 SMS™ STARR mono-stapler were significantly higher (length, p=0.003; height, p=0.004; square surface, p=0.002) compared to CPH34 HV™ STARR mono-stapler, with a 97.8% increase of prolapsectomy (p<0.001). No

intra- or early postoperative complications occurred. Transrectal sonography and autopsy detected: two (50%) small intra-parietal and two (50%) extra-rectal haematomata after Standard STARR; five small intraparietal (45.5%) and one (9%) extra-rectal haematoma after CPH34 HV™ STARR mono-stapler; three (27.2%) small intraparietal and (27.2%) extra-rectal haematomata after CPH36 SMS™ STARR mono-stapler. *Conclusion:* CPH36 SMS™ STARR mono-stapler is quite feasible both from the technological and safety standpoint; most importantly, the higher volume of prolapsectomy achievable with CPH36 SMS™ compared to standard STARR with two PPH-01™ might reduce the risk of residual/recurrent prolapse and further improve the clinical efficacy of the STARR procedure.

Obstructed defecation syndrome (ODS) is an important clinical problem mainly affecting female patients with defecation difficulty. These patients report a false sense of defecation with failure, intense straining during defecation, and a feeling of incomplete evacuation; at times they are even compelled to anal or vaginal digitation in order to complete defecation (1-7). According to the unitary theory of rectal prolapse, ODS shares a common pathophysiological feature with haemorrhoids, namely internal rectal prolapse; during defecation, this internal prolapse can descend down to the anal canal, up to or even beyond the anal verge, thus pushing out the anorectal mucosa and haemorrhoids. Over time, this dynamic prolapse weakens the supporting structures, such as Treitz's and Parks' ligaments and recto-vaginal septum, thus progressively leading to a haemorrhoidal prolapse that may be associated with recto-rectal or recto-anal intussusception. This internal rectal prolapse can also swell transversally, as demonstrated on video-defecography, thus creating a rectocele that can mechanically obstruct further defecation (8, 9).

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Moreover, rectal hyposensitivity (RH) has a definitive clinical impact on patients, with infrequency of defecation or obstructed defecation symptoms being reported with a prevalence of 23% compared to 5% in patients without constipation (10, 11). RH may be even higher (29%) in patients with obstructed defecation due to mechanical obstruction, such as rectocele or intussusception (11). This mechanical and functional obstruction causes straining during defecation, and excessive efforts increase the pressure and stress of pelvic muscles, fasciae and ligaments.

On these grounds, the surgical correction of ODS should be directed towards the correction of the internal rectal prolapse and rectocele, thus allowing not only a painless surgery but also a pathophysiologically-driven correction of the primary rectal wall alteration. Stapled transanal rectal resection (STARR) proved its efficacy in 70% to 90% of patients, at least in the short-term follow-up, with a low postoperative complication rate. This technique can remove a larger amount of internal/external rectal prolapse by means of two half purse-string sutures and, more recently, with the 'parachute' technique compared to traditional stapled haemorrhoidopexy (12-21). Nevertheless, the currently available device dedicated to STARR (PPH-01™; Ethicon Endo-Surgery, Inc., Pratica di Mare, Rome, Italy) poses some questions regarding the extent of rectal prolapse that can actually be resected. As a matter of fact, approximately 20% to 30% of patients undergoing STARR have a persistent rectocele or rectal intussusception one year after surgery (12-22).

Recently, thanks to the development of new high-volume (HV) devices, such as the CPH34 HV™ and the new CPH36 SMS™ (Chex Surgical Staplers; Frankenman International Limited, Hong Kong), wider and thicker prolapsectomy specimens can be obtained, thus reducing the risk of residual and recurrent rectal prolapse that in the long-run may hamper the dynamic process of defecation (23). From a theoretical standpoint, such new staplers would even allow the STARR procedure to be performed in a single step, using just one stapler, the STARR mono-stapler. On these grounds, a sequential experimental study was undertaken in order to test the safety of these new HV devices (CPH34 HV™; CPH36 SMS™), as well as to determine the specimen volume of prolapsectomy with the use of a STARR mono-stapler.

Materials and Methods

The first phase of this experimental study was performed on May 30th-31st 2011 at the Experimental Center of Vila do Conde, Portugal. Thirteen pigs were selected to undergo STARR by means of one CPH34 HV (Chex Surgical Staplers) (n=11) or the standard STARR procedure with two PPH-01™ (n=2). The second phase of the study was performed on January 14th-17th 2014 at the same experimental Center; 13 pigs were selected to undergo STARR by means of one CPH36 SMS™ (Chex Surgical Staplers) (n=11) or the standard STARR procedure with two PPH-01™ (n=2).

In each case, the length, height, surface area, and volume of the resected specimen were determined by the same examiner at the end of the operation; the volume was calculated using a graduated ampulla filled with saline solution by measuring the increase in volume when the surgical specimen was put into the ampulla. A histological examination was performed to define the relative percentage of mucosa, submucosa and *muscularis propria* within the surgical specimen. Pigs were clinically examined over three days before undergoing transrectal sonography in order to assess perirectal and pelvic complications (intra-parietal, extra-rectal, pelvic haematoma/abscess, dehiscence of the anastomotic line, damage to surrounding organs) and autopsy, to confirm the existence of surgically related locoregional complications. The study protocol was submitted and approved by the Ethics Committee of the Institution.

Surgical procedures. Standard STARR technique. The anal verge was gently dilated with one and then two fingers, and the lubricated circular anal dilator (CAD) with the obturator of the PPH-01™ kit was introduced and manually held in place. After removing the obturator, the operative anoscope (PSA-33) was introduced into the CAD; the posterior rectal wall was protected by a retractor that was inserted into the lower hole on the CAD and pushed along the anal canal and lower rectal ampulla. Three double-passed transversal stitches with Prolene 2-0 (Ethicon, Somerville, NY, USA), including the physiologically prolapsed rectal wall with mucosa, submucosa and rectal muscle wall, were made at least 3 to 4 cm above the dentate line at 3, 9, and 12 h in gynecologic position. The PPH-01™ was opened and the anvil was placed above the stitches whose ends were knotted (three on each side) in order to be brought through the two lateral holes of the stapler. Examination of the posterior vaginal wall was not possible, as in humans, in order to prevent vaginal mucosa entrapment. While the ends of the sutures were kept in traction, the stapler was closed, fired, and then withdrawn. The minimal mucosal bridge with a staple connecting the two edges of the anterior anastomosis was cut by scissors, with two more stitches applied at its lateral extremities and a third stitch applied at 6 h in order to perform the posterior prolapse resection, with the retractor inserted into the upper hole of the dilator. Subsequent surgical manoeuvres with the stapling device were similar to those of the previous phase. After careful inspection for bleeding of the anastomotic line, with haemostatic stitches (Vicryl 3-0; Ethicon) being applied where required, the operation was completed by positioning a dry artificial sterile sponge of fibrin in the ano-rectal canal for 4 to 6 h, and the CAD was removed.

STARR mono-stapler. After the introduction of the CAD, as previously explained, the operative anoscope was introduced into the lumen of the CAD, and a 2-0 Prolene purse-string suture was made at least at 3 to 4 cm above the dentate line to make the anastomotic line at the end of the procedure approximately 2 to 3 cm proximal to the dentate line. Two stitches were added at 6 and 12 h, applied over the purse-string to apply tension to it in order to ease the introduction of the anvil of the stapler, due to the limited anatomic space in-between the ilio-pelvic bones. Hence, the anvil of the stapler was introduced fully open proximal to the purse-string that was tied with a closing knot. The stitch made at 12 h was removed, while the ends of the suture threads of the purse-string and those of the stitch made at 6 h were knotted together on each side to form a small parachute, and pulled through the lateral holes

of the instrument; the ends of the sutures were then fixed externally with a clamp. Gentle digital pressure on the sutures was maintained while tightening the stapler to draw the prolapsed rectal wall into the stapler casing. The stapler was then fired in order to perform the prolapsectomy. Haemostatic stitches were placed along the anastomotic line in re-absorbable material (Vicryl 3-0) where required, and their number was recorded in the operative description. After prolonged observation to check for haemostasis, an absorbable plug was placed in the anal canal, thus concluding the intervention.

Statistical analysis. Descriptive statistics, including mean and standard deviation (SD), were computed for all quantitative variables. Student's t-test was used to evaluate differences in means between different groups, Levene's test was used for testing homogeneity of variances. Reported *p*-values were two-sided, and values of less than 0.05 were considered statistically significant.

Results

The operations were always carried-out by two surgeons (G.R. and A.C.) and the mean operative time was 15 min (SD=3.6 min). Only in one operation (Standard STARR with two PPH-01™), one stitch was applied on the anastomotic line to achieve haemostasis.

The measurements of the surgical specimens are reported in Table I. Surface measures (length, height, and surface area) of the specimens of standard STARR, considering the two samples retrieved with PPH-01™ added together, were not significantly different compared to the single specimen obtained with the CPH34 HV™ STARR mono-stapler, although the former achieved 20% higher volume of prolapsectomy ($p=0.178$). Similarly, surface measures of the specimens of standard STARR were not significantly different compared to CPH36 SMS™ STARR mono-stapler, although the latter achieved 57% higher volume of prolapsectomy compared to standard STARR ($p=0.008$). Finally, surface measures of the specimens of CPH36 SMS™ STARR mono-stapler were significantly higher (length, $p=0.003$; height, $p=0.004$; surface area, $p=0.002$) compared to CPH34 HV™ STARR mono-stapler. Moreover, the specimen volume of STARR mono-stapler with CPH36 SMS™ was 97.8% higher compared to that using CPH34 HV™ STARR mono-stapler ($p<0.001$). Regarding the histological examination, the surgical specimens were always represented by normal ano-rectal wall including mucosa, submucosa and *muscularis propria*, with a mean percentage of *muscularis propria* greater than 60% of the whole specimen.

No intraoperative or early postoperative complication occurred. Transrectal sonography and autopsy were always performed by the same operator (J.M.) on the fourth postoperative day, and there was a more than satisfactory agreement of the findings obtained with these two examinations (Table II). Among the 4 pigs undergoing standard STARR with 2 PPH-01™, 2 had a small intraparietal

Table I. Length, height, surface area, and volume of prolapse resection in the three different groups.

	Length (mm)	Height (mm)	Surface area (cm ²)	Volume (ml)
STARR/PPH-01™				
Case 1	120	70	84	13.5
Case 2	110	60	66	13.0
Case 3	90	35	31.5	10.5
Case 4	105	55	57.75	18.0
Mean (SD)	106.25 (12.5)	55 (14.7)	59.8 (21.8)	13.7 (3.3)
SMS/CPH34 HV™				
Case 1	100	45	45	13.0
Case 2	90	45	40.5	11.0
Case 3	90	40	40.5	10.5
Case 4	100	45	45	11.0
Case 5	105	40	42	11.5
Case 6	85	35	29.75	10.0
Case 7	85	30	25.5	10.0
Case 8	80	45	36	10.5
Case 9	100	40	40	11.0
Case 10	100	45	45	12.0
Case 11	90	40	36	10.5
Mean (SD)	93.18 (8.1)	40.9 (4.9)	38.2 (6.3)	10.9 (1.0)
SMS/CPH36 SMS™				
Case 1	90	40	36	13.0
Case 2	105	35	37.25	14.0
Case 3	105	50	52.5	24.0
Case 4	100	50	50	24.0
Case 5	95	45	42.75	18.0
Case 6	120	50	60	21.0
Case 7	95	50	47.5	23.0
Case 8	120	55	66	24.0
Case 9	120	55	66	24.0
Case 10	120	55	66	26.0
Case 11	120	55	66	26.0
Mean (SD)	108.18 (12.0)	49.0 (6.6)	53.6 (11.9)	21.5 (4.5)

haematoma, and 2 an extrarectal haematoma, with one of them having also a staple within the posterior wall of the vagina. Among the 11 pigs undergoing CPH34 HV™ STARR mono-stapler, 5 had normal findings, 5 had a small intraparietal haematoma, and 1 had an extrarectal haematoma. Finally, out of 11 pigs undergoing CPH36 SMS™ STARR mono-stapler, 5 had normal findings, 3 had a small intraparietal haematoma, and 3 had an extrarectal haematoma.

Discussion

The pathophysiology of ODS has yet to be clearly defined because anatomical defects, such as internal rectal prolapse, and rectocele, may be associated with functional alterations although none of them can be regarded *per se* as pathognomonic of the disease (1-7). According to the unitary theory of rectal prolapse, a common pathophysiological thread can be found between patients with haemorrhoidal

Table II. *Transrectal sonography and autopsy findings on the fourth day after prolapse resection in the three different groups.*

	PPH-01™ Standard STARR		CPH34HV™ STARR mono-stapler		CPH36 SMS™ STARR mono-stapler	
	No.	Size (mm)	No.	Size (mm)	No.	Size (mm)
Transrectal sonography						
Normal findings	-		5		5	
Intraparietal haematoma	2	3-15	5	4-11	3	7-10
Extrarectal haematoma	2	16-38	1	21	3	20-37
Pelvic haematoma	-		-	-	-	
Injury to surrounding organs	1 (vagina)		-	-	-	
Dehiscence of the suture line	-		-	-	-	
Autopsy data						
Weight of the animal (Kg)*	44.5 (1.5)		42 (1.8)		50 (2.7)	
Intraparietal haematoma	2	6-18	5	5-13	3	6-12
Extrarectal haematoma	2	17-42	1	23	3	20-41
Pelvic haematoma	-		-		-	
Injury to surrounding organs	1 (vagina)		-		-	
Dehiscence of the suture line	-		-		-	
Thickness of the rectal wall*		13 (1.1)		12 (1.7)		12 (1.3)
Suture line-to-anal verge distance*		38 (2.1)		40 (2.4)		39 (1.9)

*Data are the mean (standard deviation).

prolapse and ODS, namely internal rectal prolapse. In patients with ODS, the internal rectal prolapse can also swell transversally, as demonstrated at video-defecography, thus creating a rectocele that can mechanically further obstruct defecation (8-9, 24).

For these reasons, the correction of internal rectal prolapse and rectocele, by means of STARR, proved effective in 88% to 95% of patients, at least in the short-term follow-up, with a low post-operative complication rate (12-17, 21). These results were not confirmed in other studies, with an improvement limited to 56% to 65% of patients, coupled with a high rate of re-intervention (24.3%) both for recurrent disease and treatment-related complications (18-20, 25-26). These controversial observations may be explained by: i) limited clinical experience on STARR, with rather few cases recruited within each Institution; ii) inter-operator differences in expertise in stapler-assisted transanal surgery; iii) non-uniform inclusion/exclusion criteria for patients, and iv) residual/recurrent rectal prolapse/rectocele in up to 20% to 30% of patients one year after surgery (12-22). It is noteworthy that, a complete and stable correction of rectocele is fundamental in patients undergoing STARR in order to obtain satisfactory clinical results because by increasing rectal sensitivity, the perception of rectal fullness is restored and translates into an improvement of obstructed defecation symptoms and patient satisfaction index (17).

In order to overcome the issue of incomplete prolapse resection achievable with the currently available device (PPH-01™) dedicated to standard STARR, a new surgical

technique using the CCS-30 Contour Transtar™ device has been proposed (27). The preliminary results on the few hundreds of patients treated with this new technique suggest that the specimen volumes are actually almost double in patients undergoing STARR with CCS-30 Contour Transtar™ device compared to standard STARR, although this did not translate into an improvement of patient satisfaction index, and was associated with a consistent risk (3-15.7%) of serious postoperative complications, such as: spiralling resection with secondary rectal stenosis, recto-vaginal fistula, rectal perforation, anastomotic dehiscence, postoperative bleeding, and impaired continence (28-33).

Recently, new HV devices have been tested; however, prolapsectomy performed with only one CPH34 HV™ achieved approximately 10% to 20% less volume of prolapse resection compared to a standard STARR procedure with two PPH-01™, thus being more than effective for performing a stapled haemorrhoidopexy in patients with medium to large internal rectal prolapse but not enough for a STARR mono-stapler (23). This highlighted the need for a new device with a larger stapler casing, CPH36 SMS™, with the aim of performing the STARR procedure in a single step, using just one stapler, in order to avoid the complexity of STARR with the CCS-30 Contour Transtar™ device.

Our findings support the hypothesis that the use of a STARR mono-stapler is quite feasible from both the technological and safety standpoints because CPH36 SMS™ generally achieved a 57% higher volume of prolapsectomy compared to standard STARR with two PPH-01™, and this

might aid in reducing the risk of residual/recurrent prolapse. Moreover, few side-effects were observed; in fact, the small intraparietal and extrarectal haematomata that were reported in 6 out of 11 pigs treated with CPH36 SMS™ STARR mono-stapler were likely related to the difficult introduction of the anvil of the stapler into the limited anatomical space in between the ilio-pelvic bones of the pigs rather than to insufficient haemostatic properties of the stapler, because no stitch was required to complete the haemostasis of the anastomotic line, or to a traumatic effect of the stapler itself. Actually, despite the significantly higher volume of prolapsectomy achieved with CPH36 SMS™, no damage to surrounding organs occurred because the wider stapler casing, coupled with its greater compliance, enables the easy introduction of the prolapsed tissue into the case of the device without any excessive traction.

Moreover, we clearly demonstrated that the new CPH36 SMS™ allowed a resection almost double in volume compared to CPH34 HV™, under similar experimental conditions, thus meaning that its technological features define CPH36 SMS™ as a dedicated HV for STARR mono-stapler. This would imply a great advantage not only from the economic standpoint but also due to the great simplification of the surgical procedure that was very similar to a stapled haemorrhoidopexy, with reduced operating times and fewer postoperative complications.

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None of the Authors has any conflict of interest, with the exception of Professor Reboa whose possible conflict of interest is related to the technological innovations suggested for the development of CPH36 SMS™.

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