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STARR Single Stapler? yes, we can. Starrone: Stapled Trans-Anal Rectal Resection with only one High-Volume Device. Review of 155 Personal Cases from 2009 to 2021 Nando Gallese*

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1. Summary

The methods of Stapled Trans-Anal Rectal Resection, STARR and Transtar, designed and proposed by Antonio Longo, widley used, present some problems and difficulties. Many Authors have sought alternatives able to optimize the results, to limit the risk of complications, to facilitate the operations, to reduce the operating times, to lower the economic costs. Single stapler resection of prolapse and rectocele only on anterior rectal wall was often cause of asymmetry and bad functional results. on the bases of personal experience at 2009, with 1398 stapled anopexys (Longo Operation) + 262 STARR/Transtar, the Author proposed, since 2009, a personal variant to STARR with a single high-volume circular stapler, defined StarrOne. After 12 years Author expose results of the review of 155 personal cases The main times of the technique are briefly described, pointing out the characteristics of the device CPH34HV and the benefits that this entails. Results on cases treated allow a good evaluation of the method, in the absence of significant complications, with satisfactory technical results and positive subjective feedback from patients, with tolerable discomfort and sequelae.

2. Introduction

After Antonio Longo's operations (Stapled Anopexy, STARR and Transtar) there has been a gradual run-up to the introduction of several variations of mechanical interventions for rectal prolapse, in order to facilitate the surgical maneuvers, to reduce the controversial and to improve the performances, optimizing technical gestures, materials and surgical times. We have moved rapidly from simple mucosectomy to the "double-stapler" and transanal

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resection of the rectum using full-thickness STARR and Transtar. STARR, despite being the most widely used method, has the disadvantage that require the use of two circular staplers, with the problem of the "ears" at the intersection of the two semicircular sutures and with the much more important problem of the possible inadequacy of the resectable portion f rectal tissue, due to the limited capacity of the device case (PPH01 J & J) [1-12]. Previously, some authors have designed a correction of prolapse and rectocele by using a single stapler, with resection of the only anterior rectal wall: the solution was not effective for the obtained asimmetry with a large redundancy of the posterior rectal wall and bad results, both anatomical and functional. The Transtar overcomes this limitation and allows resection transanal portion rectal indicated by the clinical situation and desired by the surgeon, with semicircular stapler (CCS30 J & J), but the method is restricted only to those most experts because it has more technical difficulties and needs adequate learning curve with educational training in specific theoretical and practical "steps" at highly specialized centers. Many operators would like the opportunity to have a tool that does not require repeated extractions and refills, to avoid possible and frequent imperfections and asymmetries of the rim of the suture or complications such as spiral suture, with stenosis of rectal lumen. All the techniques of stapler prolapse treatment ar subject to a certain percentage of other complications, including severe (bleeding, urgency, rectal-vaginal fistulas and other), widely known and discussed, which beyond the scope of this specific treatment. In response to the above concerns have been personally made some interventions in which it was possible to achieve rectal transanal

resection using a single circular stapler (CPH34 Chex-Healthcare), equipped with features to allow the removal of an adequate amount of bowels, easier, with reduction of the operative time and of economic burden. This procedure was defined Starr0ne (Stapled Trans-Anal Rectal Resection only-one Stapler).

3. Cases Review - Materials and Methods

155 patients were recruited from 2009 to 2021 at the Proctological Surgery Unit and Perineum Diseases Hub "Sardinia" of the Sant'Antonio Hospital in Cagliari (Italy) and underwent StarrOne operation with high volume circular suture devices (Table 1).

 Table 1: 155 patients were recruited from 2009 to 2021 at the Proctological Surgery Unit and Perineum Diseases Hub "Sardinia" of the Sant'Antonio

 Hospital in Cagliari (Italy) and underwent StarrOne operation with high volume circular suture devices.

Starr0ne 2009-2021								
Device	СРН32	CPH34	4 СРНЗ	СРН34-НV		HST36	CPH36-SMS	Tot
Year								
2009	2	4						6
2010		2						2
2011		4	2					6
2012		8	5					13
2013			5	1				6
2014			2	3				5
2015			3	4				7
2016			4	6				10
2017			21	1				22
2018			13					13
2019			28					28
2020			11					11
2021			25				2	27
тот	2	18	119	15	;		2	156

3.1. Patient Selection Criteria

1. Constipation score (Wexner test) 0/30

2. Incontinence score (CCF - Cleveland Clinic Fecal incontinence) 0/20

3. Clinical examination of the posterior, middle and anterior perineal compartments

4. Colonoscopy

- 5. Defecography
- 6. Anorectal manometry

7. Transanal ultrasound with 360 ° rotating probe

1-2-3-4 tests required for all patients

Exams 6-7 + others (Intestinal Transit Times with Radiopaque Markers, pelvic-dynamic MRI, etc) only as needed

3.2. Inclusion Criteria

1. Constipation score > 7

2. Colonoscopy substantially regular or with pathologies not affecting the procedure

3. Defecography with confirmation of prolapse, intussusception,

descending perineum, rectocele, incomplete emptying

4. Anesthesiological risk max ASA3

3.3. Possible Exclusion Criteria (All Relative, with Individual Patient Assessment)

1. Incontinence score > 5

2. Massive enterocele

3. Previous anorectal surgery with retracting, deforming, stenosing scars or anastomotic dehiscence

4. ASA 4-5 or other generic contraindications to anesthesia or surgery

3.4. Follow Up

1. 1 month (clinical examination)

2. 3 months (clinical examination)

3. 6 months (clinical examination, proctoscopy)

4. 12 months (clinical exam, proctoscopy, other as needed)

5. Subsequent annual checks up to 5 years

3.5. Result Indicators

1. Complications - bleeding and postoperative pain (VAS), suture dehiscence, incontinence or urgency, constipation

2. Time of hospitalization and convalescence and return to normal social life

3. Late complications - bleeding with anemia, mucorrhea, chronic pain, prolonged defecatory urgency

4. Temporary or definitive objective persistence of clinical signs of constipation (laxatives, enemas, typing, etc.)

5. Subjective perception of outcomes - satisfied, satisfied, dissatisfied, altered stable QoL

3.6. Cataloging of Results

1. Patients recovered or almost totally improved

2. Patients improved, but with persistent attenuated symptoms

- 3. Patients not improved
- 4. Worsened patients

5. Need for re-interventions

3.7. Cases Review - Results

Patients enrolled 155 in 12 years from 22 September 2009 to 30-11-2021

Males 40 (25.8%)> 16 with LUTS and of these 7 with TURP

Females 115 (74.2%) 32 with previous hysterectomy, 3 with surgery for Total Pelvic Organs Prolapse

Age 18 to 89 (mean 56)

Patients with previous anorectal operations 41

Milligan Morgan 19

Longo 8

Re-STARR 6 Re-Transtar 2

POPS (laparoscopic suspension of pelvic organs prolapse) 3

Colorectal resection for cancer 3

Patients reoperated after Starr0ne 2

1 with anal fissure and stenosis + 1 with voluminous anastomotic reactive polyp

Histological examination

Rectal Carcinoma or IBD never diagnosed

Measurement of the removed full thickness rectal segment

4 to 12 cm (average 6 cm)

Post-operative discomfort with spontaneous resolution

Bleeding 4%, severe pain 21%, prolonged pain 9%, short urgency 38%, prolonged urgency 8%

Major complications

Re-hospitalization for bleeding 4

Need for blood transfusion 1

Perirectal and retroperitoneal hematoma 1 (spontaneous resolution)

Chronic pelvic pain (aggravation of pre-existing) 2

Anastomotic dehiscences 0

Appearance or aggravation of incontinence 0

(in 4 cases improvement of incontinence due to reduction of Inhibitory Rectal-Anal Reflex)

Need for urgent re-intervention 0

The patients all underwent spinal anesthesia

Intervention time ranged from 25 to 65 minutes (mean 35)

The hospital stay lasted for 4 days: Monday for examinations and preparation, Tuesday for surgery, Wednesday for nutrition, walking and control of physiological functions, Thursday for blood tests for control and discharge.

Only in 2 cases, for non-serious reasons, but for the personal needs of the patients (one very old, the other extremely emotional) was the hospital stay extended up to 6 and 9 days respectively.

Patient satisfaction was total in 32% of cases, partial in 57%, poor in 6%, zero in 5%.

In the cases of slightly or totally dissatisfied patients, clinical and instrumental checks are continued (Colonoscopy, Defecography, Dynamic Pelvic MRI, Anorectal Manometry, Transanal Ultrasound, Neurological, Orthopedic, Uro-Gynecological and Pain Therapy consultancy) and sphincter and pelvic floor rehabilitation is practiced by means of Bio Feedback, Electrostimulation, Sacral Neuromodulation).

The other patients, at the end of the checks of the first year after Starr0ne, were invited to annual visits up to the fifth year.

4. Conclusions

To date Author's personal experience amounts to over 10700 colon-rectal-proctological interventions, including more than 1500 stapled anopexis (Longo's operation) and more than 400 stapled trans-anal rectal resection STARR, Transtar, and Starr0ne (155). The stapler CPH (Chex-Healthcare), very similar to models PPH (J & J), already widely in use, allows to perform a rectal transection appropriate to the therapeutic needs with a single shot stapler, according to some peculiarities:

- high-capacity case = high volume of resectable tissue
- 4 longitudinal grooves = uniform traction on prolapse

- large agrafes number with optimal sealing and large caliber of the suture = lower incidence of dehiscences, bleedings, stenosis

- kit with circular CAD and alternate incomplete in 2 quadrants of the circle = adaptable to the pelvis measures
- "Wings" on the knob closure = ergonomic screw
- 32/34/36 mm calibers = choice adaptable to the needs

In case of obstructed defecation for invaginated prolapse and rectocele is possible a transanal mechanical rectal resection (STARR) through the use of a only one circular High-Volume stapler with large size, large capacity, large versatility (StarrOne). The controls of the 155 cases treated so far allow a good preliminary evaluation of the method, in the absence of significant complications, with satisfactory technical results and positive subjective feedback from patients, with tolerable discomfort and sequelae, which closely follow the trend of the more proven interventions STARR and Transtar, but the StarrOne improves the performance efficiency of these interventions in all aspects. It is not possible to accurately determine the indications and limits of this method, which depends on the patient's individual assessment and the specific clinical situation: the Author believes, in the light of his own experience, that the STARR double stapler can be considered potentially outdated, since the StarrOne pursues the same objectives, with the same results, but with greater technical ease and with half the cost using "a single stapler". The Transtar preserves a validity for the larger prolapses, those ones where the bottom edge of intussusception exceeds more than 3-4 cm the outer limit of the CAD and therefore reach a volume that could not be fully contained, despite the wide capacity, even in the case of a CPH High-Volume stapler. For total external larger prolapses the better choose and the primary indication remains the Altemeier's operation.

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