

Original Research Article

A randomized controlled study comparing the outcome of laparoscopic totally extra peritoneal repair versus Desarda repair in the management of inguinal hernia

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ABSTRACT

Background: Desarda repair is a technique of a tissue based tension free mesh free inguinal hernia repair, shown to be comparable to the standard Lichtenstein repair. Till date, no study has been done comparing Desarda repair with laparoscopic total extra peritoneal repair (TEP), hence this study was planned.

Methods: The prospective randomized controlled study was done over a period of 18 months, and included a total of 50 patients, randomly allocated into 2 groups: TEP (group 1) and Desarda repair (group 2), 25 in each group, and followed up for a period of 1 year.

Results: Chronic inguinodynia, including groin stiffness showed a statistically significant difference between the 2 groups ($p=0.02$). Foreign body sensation (16% in TEP group and none in Desarda group) and recurrence rate (12% in TEP group and none in Desarda group) did not show a significant difference. The operating time in the Desarda group (66.8 ± 20.35 minutes) was significantly less than TEP group (78.6 ± 11.86 minutes), with $p<0.01$. There was no significant difference in terms of post-operative pain scores (VAS scores) at five time points, post-operative analgesic requirement, hospital stay and return to normal daily routine activity or work and post-operative complications. Desarda repair was also found to be much more economical.

Conclusions: The present study establishes the potential benefits of Desarda repair over TEP in terms of shorter duration of surgery, lesser incidence of chronic inguinodynia and lesser cost of the procedure, along with the avoidance of mesh related complications.

Keywords: Hernia, Desarda, Total extra peritoneal repair, Recurrence, Chronic inguinodynia

INTRODUCTION

Inguinal hernia repair is one of the most commonly performed procedures by the general surgeons, with over 20 million hernia repairs carried out per year worldwide.¹

Tissue repair techniques like Bassini and Shouldice repair which were once the chief procedures performed became unpopular because of the high recurrence rate (0.7-1.7%

which may reach upto 15%), resulting from the tension on suture line at the site of repair.² The tension free mesh repair (Lichtenstein technique), introduced in 1984, became the most popular of the different open mesh based techniques with minimal peri-operative morbidity and low recurrence rates (4%) in the long term.^{2,3} However, the mesh related complications and chronic groin pain were often conveniently ignored and not discussed.

Laparoscopic techniques of inguinal hernia repair are still evolving as compared to open techniques in terms of complication rates and widespread acceptability among surgeons due to steep learning curve. Laparoscopic hernia repair has been marketed over conventional open mesh hernia repair in being less painful, resulting in early ambulation, early return to work and better cosmesis, all of which are associated with greater patient satisfaction.

Both Lichtenstein repair and laparoscopic hernia repair require mesh placement, however mesh has its own set of associated complications beside the cost of the mesh. Mesh implantation in the inguinal region can result in chronic inguinodynia such as foreign body sensation in the groin, discomfort and abdominal wall stiffness. Mesh migration to the intestine, urinary bladder, femoral vein, pre peritoneal space and the scrotum has been reported after all varieties of mesh repairs.^{2,4-7} Mesh rejection has also been reported.² Surgical site infection is more frequent after mesh-based techniques for hernia repair which can culminate into mesh infection, which then becomes very difficult to eradicate, and may require mesh removal.² There is evidence of vas entrapment due to intense fibrosis after mesh placement which can lead to suboptimal fertility in young patients.²

In 2001, Indian surgeon Mohan Desarda introduced the technique of a tissue-based tension free hernia repair, without the use of mesh, with almost zero recurrence rates.⁴ The technique does not involve complicated dissection and is easy to learn.^{8,9}

Studies have been done comparing Lichtenstein versus tissue free mesh free hernia repair (Desarda repair) which showed Desarda repair is as effective as the standard Lichtenstein repair in all randomized control trials, with added advantages of shorter operating time, early return to normal gait and lower cost (no mesh).^{2,10-17}

However, there is no study comparing total extra peritoneal repair (TEP) and tissue free mesh free Desarda repair, and the present study proposes to make an attempt to compare the outcomes of the two procedures.

METHODS

The present study was a prospective randomized controlled study conducted in the Department of General

Surgery, Maulana Azad Medical College and Lok Nayak Hospital, New Delhi, from October 2016 to March 2018, for a duration of 18 months.

It included all male patients aged 18 years or above, clinically diagnosed as inguinal hernia and not falling in any of the exclusion criteria mentioned below, and willing to give consent and available for follow up.

Exclusion criteria

Complicated, recurrent, bilateral inguinal hernia, uncorrected bladder outlet obstruction, chronic cough, COPD, presence of local skin infection, previous history of lower abdominal surgery, patients unfit for general anaesthesia, complete hernia were excluded from the study.

Patients were randomized into 2 groups by computer generated random numbers and those numbers were placed in sealed envelopes, which were opened in the operation theatre just before giving anaesthesia. Two groups were created which are as follows:

Group A

Underwent laparoscopic totally extraperitoneal repair under general anaesthesia.

Group B

Underwent Desarda repair under spinal anaesthesia.

A detailed proforma was filled for each patient which were included as demographic details of the patient, relevant clinical history, general physical examination and local examination, investigations needed for fitness for surgery and details of the surgery, including operative procedure done, type of anaesthesia given, duration of the surgery (from skin incision to closure), intra operative findings and complications, if any.

For post-operative pain charting, the visual analogue scale (VAS) pain scoring chart, numbered from 0 to 10 was explained and discussed with the patient preoperatively (Figure 1).

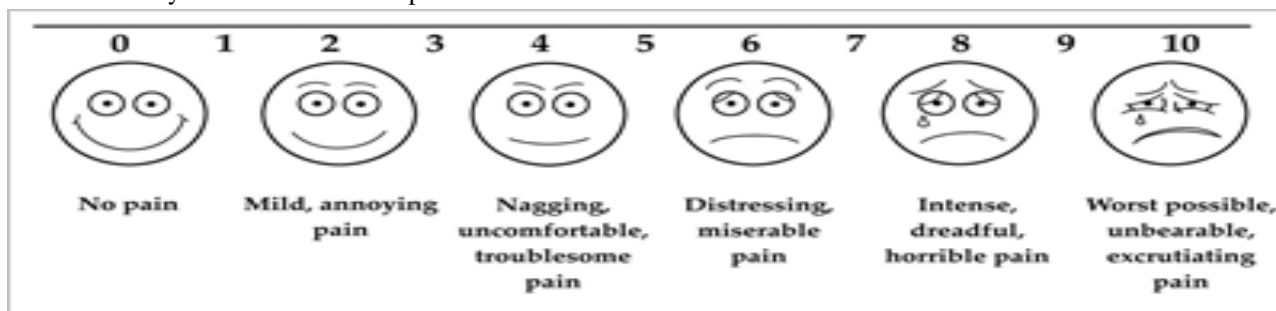


Figure 1: VAS pain scoring.

Operative procedures

Laparoscopic TEP

The procedure was done by the standard three port technique. A 10 mm infra umbilical port was introduced into the pre peritoneal space, and carbon dioxide insufflation was started at a pressure of 12-15 mm Hg. The 0° telescope was inserted through this port and was used for blunt dissection and development of the pre peritoneal space, later used as camera port. The other two 5 mm ports were inserted under camera vision in the midline, one 5 mm port 1 cm above the pubic symphysis and the other between the first and the second port, after. A 10 × 12 mm polypropylene mesh was used, rolled in zigzag fashion and loaded via 10 mm port and unrolled. Only 2-3 tackers were used for mesh fixation.

Desarda repair^{2, 4, 9}

The skin and fascia were incised using a regular, oblique inguinal incision to expose the External oblique aponeurosis (EOA). The EOA was cut in line with the upper crux of the superficial ring and the upper and lower leaves of the EOA were raised and held in hemostat. The lower flap was raised till the shelving edge of the inguinal ligament. The cord was lifted in umbilical tape and lateralized. The sac was identified, isolated from the cord structures till the deep ring, contents reduced, ligated at the neck and excised in indirect hernias, while it was inverted and pushed back into the peritoneal cavity in direct hernias. The posterior wall of the inguinal canal was strengthened by approximating the aponeurotic extensions from the conjoint muscle in the area where they were deficient (Figure 2). This step was not originally described by Dr. Desarda. The upper leaf of the EOA was sutured with the shelving edge of the inguinal ligament from the pubic tubercle to the deep ring using monofilament polydioxanone number 1 suture, in a continuous fashion (Figure 3). The first two sutures were taken through the anterior rectus sheath and the last suture was taken so as to narrow the abdominal ring sufficiently without constriction. An incision was made in this sutured medial leaf, partially separating a 2 cm wide strip. This incision was extended medially up to the pubic symphysis and laterally 1-2 cm beyond the deep ring. The medial insertion and lateral continuation of this strip were kept intact. A strip of the EOA was thus available, the lower border of which was already sutured to the inguinal ligament (Figure 4). The upper free border of the strip was sutured to the internal oblique with monofilament polydioxanone number 1 interrupted sutures all along its length (Figure 5). This resulted in the strip of the EOA being placed behind the cord to form a new posterior wall of the inguinal canal. The strip was otherwise without any tension at rest, thus making this repair “tension free mesh free hernia repair”. The spermatic cord was placed in the inguinal canal and the inferior leaf of the EOA was sutured to the newly formed superior leaf of the EOA in front of the cord using monofilament polydioxanone

number 1 continuous sutures, followed by routine closure of the superficial fascia and the skin.

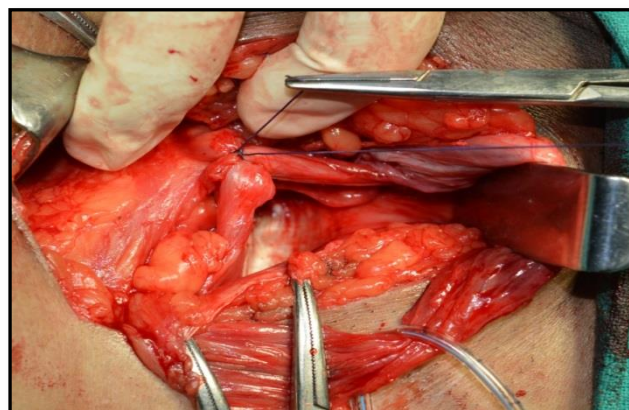


Figure 2: Posterior wall strengthened by approximating the aponeurotic extensions from transversus abdominis in the area where they were deficient.

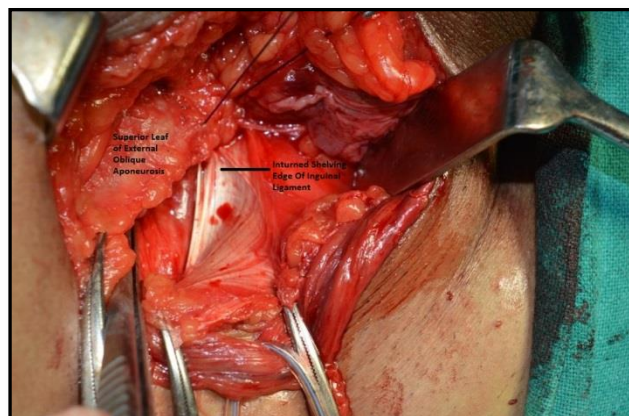


Figure 3: Superior leaf of external oblique aponeurosis sutured to the inturned shelving edge of inguinal ligament.



Figure 4: Isolation of a 2 cm strip of external oblique aponeurosis, the lower border of this strip is sutured to the inguinal ligament.

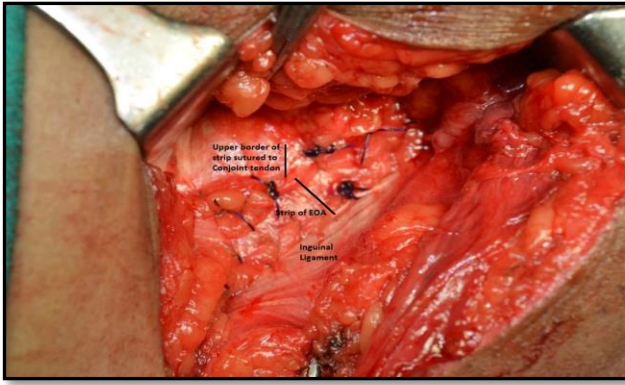


Figure 5: The upper free border of the strip sutured to the conjoint tendon using interrupted number 1 monofilament polydioxanone suture.

All the patients received injectable diclofenac 75 mg intravenously just after the surgery, at 8 p.m. on the day of surgery and at 6 a.m. on post-operative day 1. Any additional requirement was recorded. All the patients were discharged on oral diclofenac 50 mg to be taken twice a day for 3 days. Patients were told to write down any additional analgesic requirement that was later recorded on the follow up visits. The patients were discharged when they were able to perform their daily routine activities without pain. All the patients were advised to follow up in surgical outpatient clinic post operatively at 1 week, 3 weeks, 3 months and 1 year or earlier if symptomatic. The following parameters noted post operatively.

- Duration of hospital stay and time to return to normal daily routine activity such as bathing, walking around the house, etc.
- Type and total duration of analgesic requirement.
- The visual analogue pain score of each patient was assessed at 6 hours, 24 hours, 1 week, 3 weeks and 3 months after surgery.
- Time to return to work defined as time to return to complete pre-operative functional status, which included the resumption of daily routine official work (excluding heavy workers) in case of employed workers, and the resumption of daily household work in case of unemployed workers.
- Post-operative complications: Urinary retention, bleeding from suture site, pneumoscrotum, seroma formation, hematoma formation, surgical site infection (superficial or deep), as defined in the Centre for Disease Control (CDC) guidelines, scrotal edema.
- Chronic inguinodynia- groin stiffness or altered or foreign body sensation in groin 3 months or more after surgery.
- Recurrence.

A p value less than 0.05 was considered statistically significant difference.

RESULTS

The two groups were comparable in terms of mean age of patients, being 45.16±16.81 years in TEP group and 45.32±19.23 years in the Desarda group, with p= 0.97.

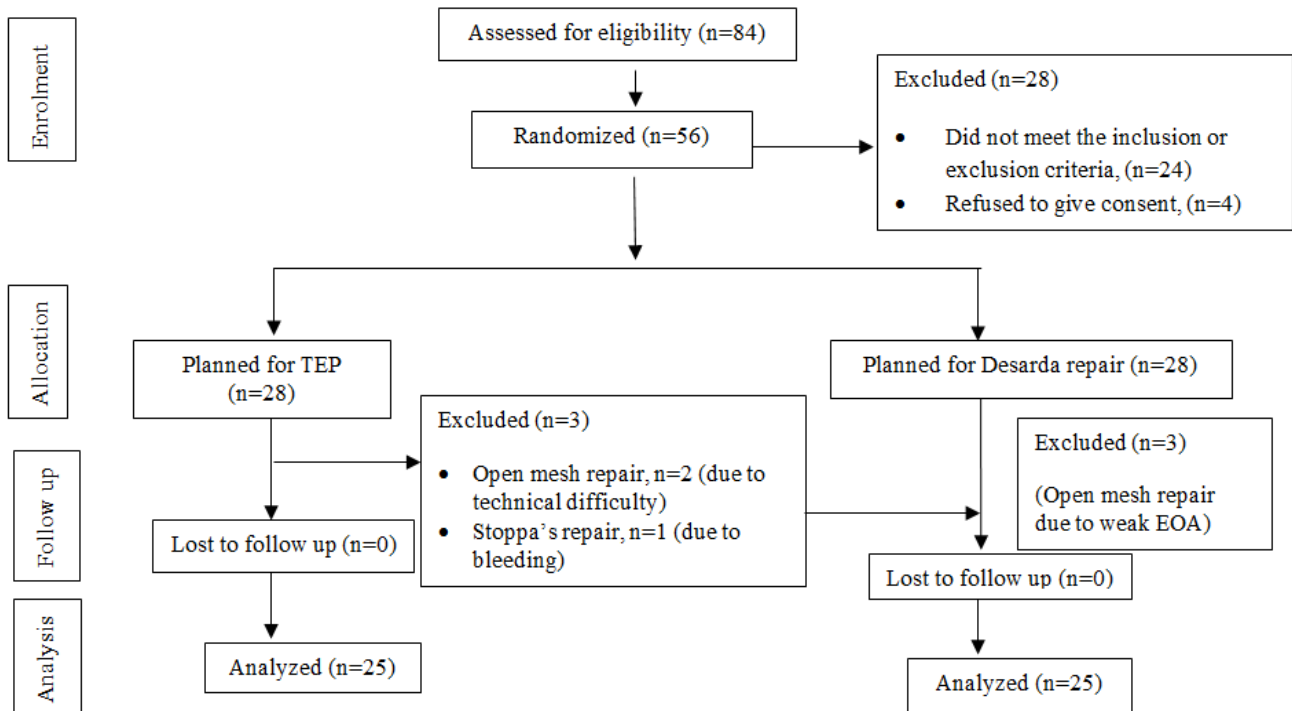


Figure 6: CONSORT statement showing the phases of a randomized controlled study.

The pain scores in each case were measured at 6 hours, 24 hours, 1 week, 3 weeks and 3 months after the surgery. The p value for the differences in mean pain scores at all the times was found to be statistically insignificant (Figure 7). The mean operating time showed statistically significant difference between the two groups, being less in the Desarda group ($p < 0.01$). The two groups were comparable in terms of total dose of additional diclofenac required for post-operative analgesia in mg, mean hospitalization time and time to return to work (Table 1).

None of the cases in either group suffered from any intra operative complication. There was no significant difference between the two groups in terms of post-operative complications (Table 2).

There was significant difference between the 2 groups in terms of chronic inguinodynia ($p = 0.02$) and stiffness in

groin ($p = 0.02$), but not in terms of foreign body sensation and recurrence rates (Table 3).

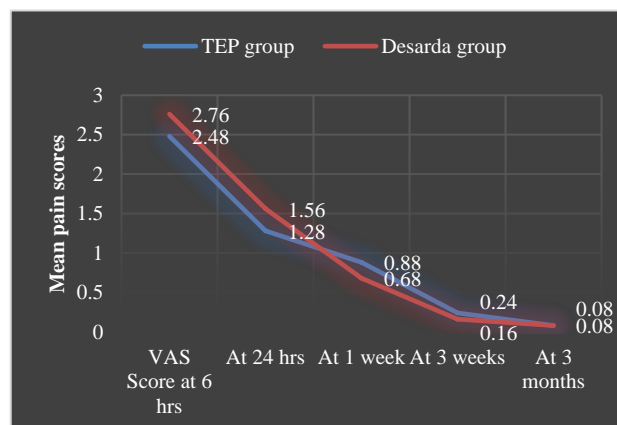


Figure 7: Comparison of mean VAS pain scores in both the groups at 5 time intervals.

Table 1: Comparison of TEP and Desarda groups on intra and post-operative variables.

Variables	TEP group (n= 25)	Desarda group (n=25)	P value
Mean operating time (minutes)	78.60±11.86	66.80±20.35	<0.01
Total additional analgesic dose required (mg)	278.0±337.91	167.0±261.47	0.20
Mean hospitalization time (days)	2.48±1.56	2.24±0.93	0.66
Mean time to return to work (days)	5.68±3.89	4.32±2.53	0.18

Table 2: Comparison of post-operative complication rates between TEP and Desarda groups.

Post-operative complications	TEP group (n=25)		Desarda group (n=25)		Total		P value
	No.	%	No.	%	No.	%	
Urinary retention	0	0.0	0	0.0	0	0.0	-
Bleeding from suture site	0	0.0	0	0.0	0	0.0	-
Pneumoscrotum	4	16.0	NA	NA	4	8.0	-
Scrotal oedema	0	0.0	0	0.0	0	0.0	-
Seroma or hematoma formation	3	12.0	1	4.0	4	8.0	0.60
Surgical site infection	1	4.0	2	8.0	3	6.0	0.97
Total	8	32.0	3	12.0	11	22.0	0.08

NA - Not applicable.

Table 3: Comparing the 2 groups in terms of chronic inguinodynia and recurrence rates.

Variables	TEP group (n=25)		Desarda group (n=25)		Total		P value
	No.	%	No.	%	No.	%	
Chronic inguinodynia	6	24.0	0	0.0	6	12.0	0.02
Stiffness in groin	6	24.0	0	0.0	6	12.0	0.02
Foreign body sensation in groin	4	16.0	0	0.0	4	8.0	0.08
Recurrence	3	12.0	0	0.0	3	6.0	0.23

DISCUSSION

Desarda repair has been compared with Lichtenstein repair in many studies, which show that it is as good as Lichtenstein repair, with added advantages of shorter duration of surgery, lesser incidence of post-operative pain and avoidance of mesh related complications.¹⁰⁻¹⁷

The present study is the first study comparing Desarda repair with laparoscopic TEP.

The mean operating time was found to be significantly less in the Desarda group in comparison to the TEP group, with p value less than 0.01. The duration of surgery depends on various factors, some related to the surgery like its complexity, the anatomy encountered and

some related to the surgeon. The shorter duration of the Desarda repair can be attributed to the lack of complicated dissection, fixed steps of the surgery with little scope of modification and the absence of time consuming steps like fashioning the mesh according to the space available and placing it correctly.^{2,14} The shorter operating time confers many advantages to this technique like feasibility as a day care procedure and feasibility to be done under local anesthesia. It also becomes more suitable as an emergency procedure in cases of complicated hernias.¹⁸⁻²⁰

The pain scores were lower in the TEP group in the immediate post-operative period (first 24 hours after surgery) as compared to the Desarda group, which can be attributed to the smaller incision size in laparoscopic repair. The mean scores at 1 week and 3 weeks showed a fall in pain scores in both the groups, with greater fall in the Desarda group. The pain scores reached their minimum 3 months post operatively, showing equal mean pain scores in both the groups. It is an established fact that open procedures cause more pain and post-operative discomfort as compared to laparoscopic procedures. Both TEP and Desarda groups were comparable on the basis of their post-operative VAS scores at five time points in the study, emphasizing the fact that Desarda repair is as good as laparoscopic TEP despite being an open repair in terms of post-operative pain and discomfort. Both TEP and Desarda repair were also comparable in terms of the supplemental analgesic requirement in the post-operative period, and this is in accordance with them being comparable in terms of the post-operative VAS scores at various time intervals. The two groups were also comparable in terms of hospitalization and time to resume normal daily routine activities and time to return to work.¹⁸⁻²⁰

The overall complication rate was higher in the TEP group as compared to the Desarda group, owing to the methodology and technical difficulty of the procedure as compared to the Desarda repair; however the difference was statistically insignificant.

There was significant chronic inguinodynia ($p=0.02$) and groin stiffness ($p=0.02$) in the TEP group compared to the Desarda group which can be attributed to the fibrosis caused by mesh and the use of tackers, both of which were not used in Desarda repair. The incidence of foreign body sensation was also higher in the TEP group, but was not statistically significant. The lesser incidence of chronic inguinodynia in Desarda repair is mainly because it is a physiologically dynamic repair in comparison to TEP which is rigid and static because of the use of mesh.¹⁸⁻²⁰

In the present study, there were total 3 patients who developed recurrence during their 1 year follow up, all of them belonging to the TEP group (12%), and there was no case of recurrence in the Desarda group. The p value calculated for the same was 0.23 which was statistically

insignificant. Most of the recurrences in the Desarda group occur at the site of newly constructed deep ring.^{2,10} This can be due to a technical error in isolating inappropriate size of the strip of external oblique aponeurosis.¹⁰ In the present study, we used a strip not more than 2 cm in width. The other site of recurrence is the weakened posterior wall.¹⁰ In this study, we found similar weaknesses of the posterior wall. Aponeurotic extensions were absent at these sites and were approximated using interrupted sutures. The recurrence in TEP group can be attributed to the technical difficulty associated with it, requiring longer learning curve and experienced hands. It also depends on the size of mesh used and its fixation.

Another parameter that deserves mention is the cost effectiveness of Desarda repair. The estimated average cost of the procedure in the Desarda group was found to be Rs. 2000, while it was calculated to be Rs. 20,000 for the TEP group.

CONCLUSION

The present study establishes the potential benefits of Desarda repair over laparoscopic TEP in terms of shorter duration of surgery, lesser incidence of chronic inguinodynia, lesser cost and avoidance of mesh and related complications. It can be preferred in emergency complicated hernia surgeries, like obstruction and strangulation, where laparoscopic surgery is not feasible with high chances of mesh infection. Its main highlight remains in being a procedure that can be done in an averagely equipped setting, at a very decent cost, and by a surgeon of average expertise and without mesh, producing results that are comparable with standard established procedures. However, due to paucity of literature, larger clinical trials with longer follow up periods are required to prove its benefits and establish it as a standard of care in routine practice.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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