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A Single-Blind, Randomized Study Comparing Clinical Equivalence of Trulene® Polypropylene Mesh to Prolene® Polypropylene Mesh in Subjects Undergoing Lichtenstein Open Repair of Primary Inguinal Hernia Secured with Sutures

Vijay Hangloo, V. S. S. Naga Babu Tippana[1], Sanjoy Mohan Bhattacharya[2], Nikhil Agarwal[2], Ashok Kumar Moharana[3], T. S. Deepak[3]

Department of General Surgery, Batra Hospital & Medical Research Center, South Delhi, [1]Department of General Surgery, King George Hospital, Visakhapatnam, [2]Department of General Surgery, Ramakrishna Mission Seva Pratishthan Vivekananda Institute of Medical Sciences, Kolkata, [3]Clinical Affairs, Healthium Medtech Limited, Bangalore

Address for correspondence:
Dr. T. S. Deepak, Healthium Medtech Limited, 472D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore 560058, Karnataka, India.
E-mail: deepak.ts@healthiummedtech.com

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Abstract

BACKGROUND: Inguinal hernia is the most frequently diagnosed abdominal wall hernia. Lichtenstein open repair involving mesh fixation lowers the recurrence rate and risk of postoperative complications. This study compared the clinical equivalence of Trulene® polypropylene mesh (Healthium Medtech Limited) and Prolene® (Ethicon-Johnson & Johnson) polypropylene mesh with respect to recurrence rate of hernia in subjects undergoing Lichtenstein open repair of primary inguinal hernia, secured with sutures.

MATERIALS AND METHODS: Between September 2020 and November 2022, this multicentric, randomized (1:1), single-blind, prospective, two-arm, parallel-group study (n = 120) was conducted. The primary study endpoint, proportion of subjects having recurrence of hernia within 6 and 12 months of index surgery, was assessed. The secondary endpoints, pain score, number of analgesics, postoperative complications, operative time, length of hospital stay, need for readmission, time to resume back to normal activities and return to work, other adverse events, subject satisfaction score, and quality of life (QOL) postoperatively were also recorded.

RESULTS: During the 12-month follow-up period, no recurrence of hernia was recorded. In addition, no significant differences regarding intraoperative mesh parameters, pain score, number of analgesics, postoperative complications, operative time, length of hospital stay, readmission, time to resume normal activities and return to work, and subject satisfaction score and QOL were recorded between Trulene® and Prolene® mesh groups.

CONCLUSION: Trulene® polypropylene mesh is clinically equivalent to Prolene® polypropylene mesh. Both meshes are safe and effective for Lichtenstein open repair of primary inguinal hernia with minimal risk of hernia recurrence and chronic pain.

Keywords:

Inguinal hernia, Lichtenstein open repair, polypropylene mesh, recurrent hernia

Introduction

World Society of Emergency Surgery has classified abdominal wall hernias as groin hernias (indirect inguinal, direct inguinal, and femoral hernias) and ventral hernias (umbilical, epigastric, spigelian,

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lumbar, and incisional hernias).[1] Global prevalence of inguinal hernia (IH) is 1.7% for all age groups and 4.0% for individuals above 45 years.[2] Patients with IH are mostly symptomatic, requiring surgical cure; however, approximately 70% of asymptomatic patients also require surgical treatment within 5 years.[3] Untreated hernia affects physical as well as socioeconomic status of the patient.[4]

International guidelines for groin hernia management have recommended mesh repair either by open procedure or laparo-endoscopic repair technique.[5] The low-cost Lichtenstein tension-free technique is used for mesh-based open repair of IH, in which the mesh reinforces the posterior wall of the inguinal canal.[6] This technique results in low recurrence, complications, and morbidity.[7] Previous studies reported fewer hernia recurrence, hematoma, neurovascular and visceral injuries, and no increase in chronic pain with mesh repair.[8,9] An ideal mesh must have biocompatibility/reactivity, low risk of infection, handling convenience, longevity, and low cost. Nonabsorbable synthetic mesh is made up of polypropylene, key advantages of which include high tensile strength, ease of handling, resistance to infection, fast healing and tissue penetration, high flexibility, and minimal adhesion.[1] Although there are studies comparing polypropylene meshes with polyester or other types of composite meshes,[9,10] comparison between two commonly used polypropylene meshes is not well established. Also, many other mesh brands are accessible in Indian and global marketplaces, but unavailability of data regarding their safety and efficacy prevents the devices from achieving their full public health potential. Therefore, this study has compared Trulene® polypropylene mesh (Healthium Medtech Limited) and Prolene® (Ethicon-Johnson & Johnson) polypropylene mesh, in subjects undergoing Lichtenstein open repair of primary IH, secured with sutures.

Materials and Methods

Ethics

This study was registered in the Clinical Trial Registry of India (No. CTRI/2020/02/023307) and approved by the Institutional Ethics Committees of three participating sites. Ethical standards of the Helsinki Declaration, ICH-GCP E6 R2 guidelines, EN ISO 14155:2020 guidelines, MDR (EU) 2017/745, Indian MDR rules 2017, New Drugs and CT rules 2019, and CONSORT were followed. Prior to this study, written informed consent was obtained from all subjects.

Study design

The primary objective of this multicentric, randomized, single-blind, prospective, two-arm, parallel-group study (September 2020–November 2022) was to assess the recurrence rate of hernia in both arms at 6- and 12-month follow-up. Secondary objectives include evaluation of pain reduction, infection frequency, hernioplasty-associated short- and long-term complications, time to resume normal activities, complications related to mesh material, postoperative discomfort, and overall subject satisfaction score.

Study participants

Males (18–70 years) with uncomplicated primary IH, requiring elective surgery with mesh fixation, who had American Society of Anesthesiologists grade 1 or 2, and no previous history of anterior mesh hernia repair were included.

Subjects were excluded if they had body mass index ≥35 kg/m^2, life expectancy <1 year, prior mesh in abdominal wall, bilateral IH, femoral or strangulated hernia, recurrent hernia, active infection at/around the incision site, tuberculosis, chronic cough, bleeding disorders, osteoporosis, unstable/life-threatening conditions, cancer, ongoing cancer treatment, radiotherapy at pelvic area, immunodeficiency or immunosuppression, allergy to polypropylene/similar products, and unable to walk 500 m. Subjects, who required emergency surgical procedures or elective/emergency laparoscopic inguinal hernioplasty or in opinion of the investigator, were unlikely to comply with the study procedure and follow-ups were also excluded.

Study settings

This study was conducted at department of surgery of three tertiary health-care centers across India.

Intervention

Trulene® mesh (Healthium Medtech Limited) and Prolene® mesh (Ethicon-Johnson and Johnson) are nonabsorbable mesh, composed of polypropylene filaments of weight >85 g/m^2. Both meshes are available in Indian market for over 10 years and indicated for hernia repair.

Study procedure

Routine aseptic standard precautions were taken before, during, and postsurgery. Standard Lichtenstein repair was performed with a 6–8-cm wide mesh patch. If necessary, the mesh was trimmed to fit ideally and secured to the aponeurotic tissue overlying the pubic tubercle by a running 2/0 polypropylene suture. To fix the mesh superiorly, three to four interrupted sutures were used. The external oblique aponeurosis was closed over the spermatic cord.

Subjects were examined at screening visit (Month 3 to Day 1), undergone surgery on Day 0 (baseline), and followed up on Days 3 and 7, and Months 1, 3, 6, and 12.

Baseline characteristics

At screening visit, subject's age, ethnicity, occupation, weight, height, vital signs, medical/surgical history, alcohol, and smoking history were recorded. Physical examinations for normal appearance and clinical examinations to determine the position and type of hernia, hernial orifice diameter, type of swelling and presence of skin inflammation, impulse on coughing and reducibility of the hernia, and pain by visual analog scale (VAS) were done.

Study outcomes

Primary endpoint

The primary outcome, proportion of subjects having hernia recurrence within 6 and 12 months of index surgery, was recorded during all postoperative follow-ups. The recurrence was defined as a symptomatic or asymptomatic defect, characterized by bulge or weakness in the abdominal wall of the operated groin with herniation of abdominal contents, exacerbated by the Valsalva maneuver.

Secondary endpoints

During surgery, the investigator evaluated the mesh regarding fixation preciseness, fixation quality (grip), manipulability/comfort in use, stretch capacity or flexibility, memory, and abdominal wall compliance by rating them on a 5-point scale: (1) poor, (2) fair, (3) good, (4) very good, and (5) excellent. Type of anesthesia, surgery length, mesh size, intestinal injury, bleeding, nerve injury, spermatic cord injury, and mesh-related challenges were also recorded.

Postoperative complications, namely, organ/space surgical site infection or SSI, hematoma, seroma, dehiscence, presence of foreign body sensation, nerve injury/paresthesia, physical restriction of abdominal wall mobility, scar tenderness, adhesion formation, bowel obstruction, mesh eventration, migration and shrinkage, and palpable stiff edges of the mesh, were recorded on Days 3 and 7 and at Months 1, 6, and 12.

On all postoperative visits, pain was evaluated using VAS, on a 0–100 scale (0–4, no pain; 5–44, mild pain; 45–74, moderate pain; 75–100, severe pain). Number of analgesics, hospital readmission, length of hospital stay, return to work, and normal day-to-day activities were measured. Subject satisfaction and QOL were assessed by asking questions according to the EQ-5D-3L instrument, which comprises five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The subjects provided their health status on EQ-VAS, ranging between 0 (worst health) and 100 (best health). Both EQ-5D and EQ-VAS were recorded on screening and on Day 7 and at Months 1, 6, and 12.

Any unintended disease/injury, medical occurrence, or clinical signs, which were not reported as study endpoints, were recorded as adverse events. Furthermore, details of medications prescribed during the study period were noted.

Sample size

Based on the available evidences,[11,12] hernia recurrence rate in standard Prolene® mesh arm was assumed to be 0.57%. Assuming type I error as 5%, power as 80%, and a difference to be detected as 0.3% between hernia recurrence rates of Prolene® mesh and Trulene® mesh arms, with a margin of non-inferiority as 10% of the difference, a minimum sample size of 52 was approximated in each arm. Further, considering 20% dropout and 10% exclusion after randomization, the sample size was increased to 66 in each arm.

Randomization and blinding

Block randomization was performed with variable block length, stratified per trial site to ensure an unbiased treatment assignment in a 1:1 ratio to receive either of the two meshes. Sequentially, numbered opaque-sealed envelope technique was used to generate three random lists of the size [n = 44 (22 vs. 22)] by a freely available software, using block sizes of 4, 6, or 8. Before surgery, subjects were randomly allocated to Trulene® or Prolene® mesh, by opening a sealed envelope. The subjects were blinded to the allocation status, but not the operating staffs. However, they were strictly instructed not to reveal the allocation status at any time.

Statistical analysis

Per-protocol analysis set was used to analyze the data with SPSS (V28.0, Chicago, IL, USA). The analysis set included all subjects with complete primary endpoint data. Continuous and qualitative variables were expressed in form of mean ± SD and proportions/percentages, respectively. *t*-Test was used to analyze normally distributed data and Mann–Whitney *U* test for distribution-free data. Qualitative variables were compared using chi-square or Fisher's exact test. The primary endpoint was summarized using chi-square test as proportion/percentage of subjects with hernia recurrence. Secondary endpoints were expressed in form of mean ± SD or proportions/percentages, as required. No additional subgroup analysis was done. Significant results of the comparison between the two groups were determined by $P < 0.05$.

Results

Totally, 124 Indian males fulfilled eligibility and randomized to Trulene® (n = 61) and Prolene® (n = 63) mesh groups (September 2020–November 2021). Four subjects were excluded [Figure 1]. A total of 120 subjects were evaluated, 60 in each group.

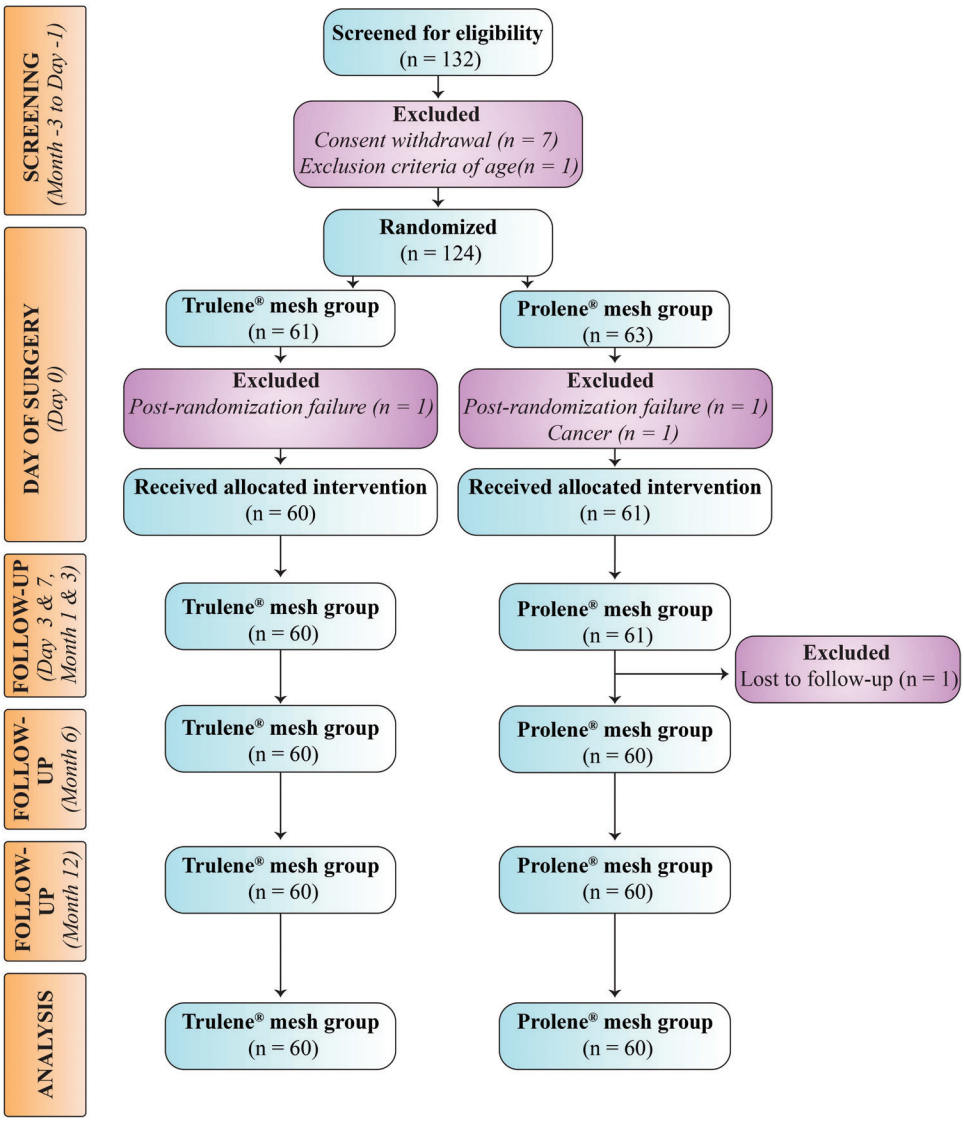

Figure 1: CONOSRT flowchart of subject enrolment and follow-up

Baseline characteristics

The groups were comparable with respect to demographics, vital signs, occupation [Table 1], and clinical examinations [Table 2]. All subjects had primary IH and localized swelling. Normal central nervous system, cardiovascular system, respiratory system, skin, ear, nose and throat, joints and extremities, and general appearance were recorded in all subjects. One (1.67%) subject in Trulene® mesh group reported constipation. One (1.67%) subject in Prolene® mesh group had B/L enlarged inguinal lymph node.

Primary endpoint analysis

At all follow-ups, no sign of recurrence of hernia following primary hernia repair was found in subjects of both groups.

Although a statistical difference ($P = 0.014$) regarding the history of alcohol consumption was observed between the groups, but the heterogeneity has not impacted the results of the primary endpoint, as the hernia recurrence rate was nil in both groups. Hence, no additional subgroup analysis was done.

Secondary endpoint analysis

Intraoperative characteristics

Intraoperative antibiotic prophylaxis was given to all subjects. No significant difference regarding intraoperative mesh parameters was observed between the groups. No "poor" score was noted for any mesh parameter [Figure 2]. Intestinal injury, nerve injury, mesh-related challenges, spermatic cord injury, and other complications were noted in neither Trulene® nor Prolene® mesh group. Other intraoperative characteristics are presented in Table 3. Both groups had good outcomes of surgery.

Table 1: Baseline characteristics of the subjects

Subject characteristics	Trulene® mesh (*n* = 60)	Prolene® mesh (*n* = 60)	*P*-value
Demographics			
Age (years), mean ± SD	48.15 ± 14.12	48.77 ± 13.78	0.40
Weight (kg), mean ± SD	64.52 ± 9.32	65.31 ± 10.02	0.33
Height (cm), mean ± SD	164.79 ± 9.21	165.41 ± 9.49	0.36
Body mass index (kg/m^2), mean ± SD	23.85 ± 3.55	23.91 ± 3.32	0.46
Alcohol consumption, *n* (%)	19 (31.67)	7 (11.67)	0.01*
Smoking history, *n* (%)	18 (30.01)	17 (28.33)	0.50
Medical/Surgical history, *n* (%)	15 (25.00)	17 (28.33)	0.84
Vital signs			
Pulse rate (per min), mean ± SD	81.42 ± 7.58	82.23 ± 9.12	0.60
Respiratory rate (per min), mean ± SD	18.02 ± 1.43	18.27 ± 1.70	0.39
Systolic blood pressure (mmHg), mean ± SD	124.38 ± 14.07	123.20 ± 11.58	0.62
Diastolic blood pressure (mmHg), mean ± SD	79.42 ± 9.31	78.75 ± 7.92	0.67
Occupation			
Desk job, *n* (%)	21 (35.00)	18 (30.00)	0.84
Hard strenuous job, *n* (%)	19 (31.67)	21 (35.00)	
Mild strenuous job, *n* (%)	20 (33.33)	21 (35.00)	

*P <0.05.

Table 2: Clinical characteristics of the subjects

Clinical characteristics	Trulene® mesh (*n* = 60)	Prolene® mesh (*n* = 60)	*P*-value
Ultrasound confirmed hernia, *n* (%)	25 (41.67)	23 (38.33)	0.85
Position of inguinal hernia			
Right, *n* (%)	36 (60.00)	34 (56.67)	1.00
Left, *n* (%)	24 (40.00)	26 (43.33)	
Classification of inguinal hernia			
Left direct inguinal hernia, *n* (%)	9 (15.00)	9 (15.00)	0.38
Right direct inguinal hernia, *n* (%)	7 (11.67)	8 (13.33)	
Left indirect inguinal hernia, *n* (%)	15 (25.00)	17 (28.33)	
Right indirect inguinal hernia, *n* (%)	29 (48.33)	26 (43.33)	
Size of inguinal hernia			
Direct hernia			0.40
<1.5 cm or 1 finger, *n* (%)	0	2 (3.33)	
1.5–3.0 cm or 2 fingers, *n* (%)	9 (15.00)	12 (20.00)	
>3 cm or more than two fingers, *n* (%)	7 (11.67)	2 (3.33)	
Not investigated, *n* (%)	0	1 (1.67)	
Indirect hernia			
<1.5 cm or one finger, *n* (%)	4 (6.67)	3 (5.00)	
1.5–3.0 cm or two fingers, *n* (%)	34 (56.67)	31 (51.67)	
>3 cm or more than two fingers, *n* (%)	4 (6.67)	8 (13.33)	
Not investigated, *n* (%)	2 (3.33)	1 (1.67)	
Hernial orifice diameter (cm), mean ± SD	2.51 ± 1.24	2.38 ± 1.04	0.54
Skin inflamed over swelling, *n* (%)	21 (35.00)	18 (30.00)	0.70
Impulse on coughing, *n* (%)	51 (85.00)	48 (80.00)	0.63
Reducibility, *n* (%)	47 (78.33)	45 (75.00)	0.83

Postoperative characteristics

No incidents of organ/space SSI, hematoma, foreign body sensation, nerve injury/paresthesia, adhesion formation, mesh eventration, migration and shrinkage, and swelling and infection (at Month 3) were recorded during the study duration. Seroma in one (1.67%, $P = 0.99$) subject of Trulene® mesh on Day 3 and a small dehiscence in one subject (1.67%, $P = 0.99$) of Prolene® mesh on Day 7 were recorded. On Day 3, in both groups, mild physical restriction of abdominal wall mobility in 1 (1.67 vs. 1.67%, $P = 1.00$) subject and scar tenderness in 12 (20.00 vs. 20.00%, $P = 1.00$) subjects were observed. In Trulene® and Prolene® mesh groups, scar tenderness rate was decreased to one and two (1.67 vs. 3.33%, $P = 0.88$) on day 7, and one and zero (1.67 vs. 0%, $P = 0.93$) after 1-month follow-up. In Trulene® and Prolene® mesh groups, one and one (1.67 vs. 1.67%, $P = 1.00$) cases of mild bowel obstruction on Day 3, and four and nine

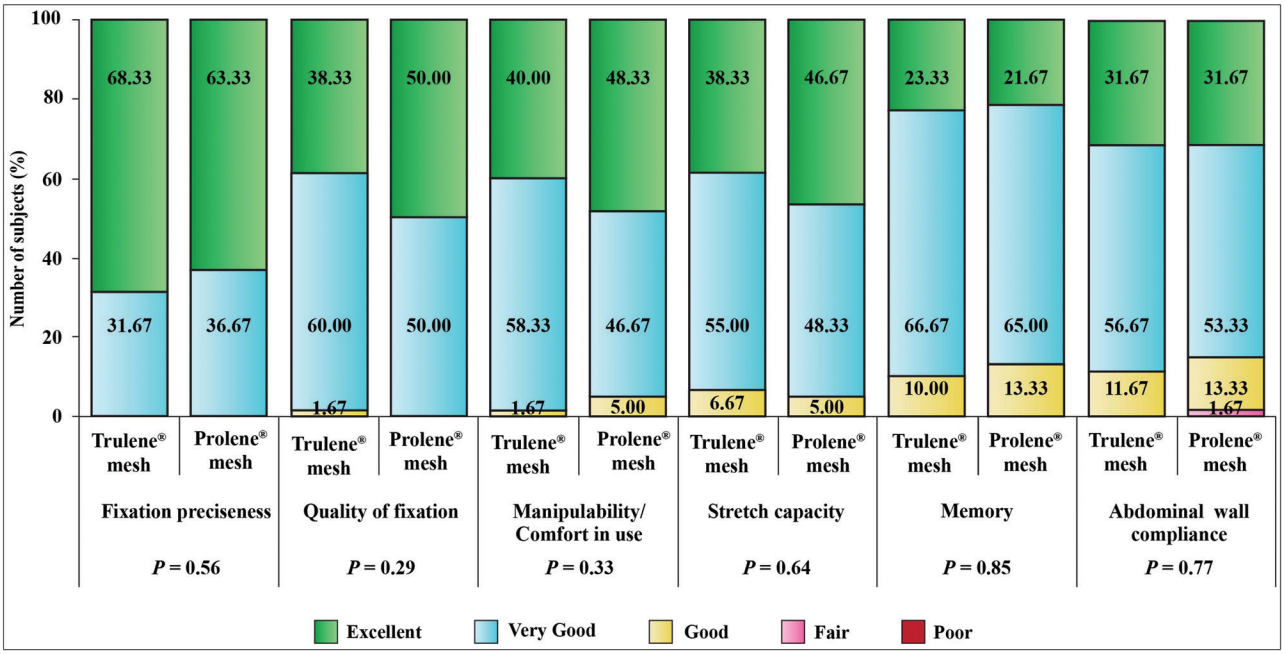

Figure 2: Graphical representation of intraoperative mesh parameters [Trulene® mesh (*n* = 60) and Prolene® mesh (*n* = 60) group]

Table 3: Intraoperative and postoperative characteristics

Subject profile	Trulene® mesh (*n* = 60)	Prolene® mesh (*n* = 60)	*P*-value
Intraoperative			
General anesthesia, *n* (%)	4 (6.67)	3 (5.00)	0.70
Spinal anesthesia, *n* (%)	56 (93.33)	57 (95.00)	
Length of surgery (min), mean ± SD	76.55±20.59	77.00±25.23	0.91
Size of mesh (cm²), mean ± SD	57.11±39.89	59.00±40.24	0.80
Postoperative			
Onset of pain (h), mean ± SD	3.75±2.76	3.94±2.04	0.68
Duration of ICU stay (days), mean ± SD	0.18±0.39	0.23±0.43	0.51
Duration of hospital stay (days), mean ± SD	4.27±1.68	4.15±1.57	0.69
Return to normal day-to-day activities (days), mean ± SD	5.88±3.76	5.50±3.31	0.56
Return to work (days), mean ± SD	15.33±8.86	14.80±6.20	0.70

(6.67 vs. 15.00%, P = 0.77) cases on Day 7 were noted that reduced to zero and one (0 vs. 1.67%, P = 0.99) at Month 1 visit. On Day 3, mild palpable stiff edge of the mesh was recorded in one (1.67%, P = 0.99) subject of Trulene® mesh group. Only 1 (1.67%, P = 0.99) subject of Trulene® mesh group reported fever (for 2–3 days) at Month 3. Based on requirement, standard nonsurgical medical treatment was provided to all subjects with postoperative complications. By Months 6 and 12, none of the complications was observed in both groups. In addition, no hospital readmission was required in both groups during the study period.

The postoperative pain VAS score as well as pain intensity (severe/moderate) were reduced with each follow-up and were comparable between the groups [Figure 3a and c]. In both groups, the requirement of analgesics was also reduced [Figure 3b]. The onset of postoperative pain and other postoperative data were comparable between the groups [Table 3]. In the analysis of five QOL dimensions, the number of subjects with no, some, and extreme problems were comparable between the groups. The high prevalence of some problems (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) during screening was reduced with each follow-up [Figure 4]. The mean EQ-VAS score was also improved with each follow-up and was comparable between the groups [Figure 5].

During the study period, 37 device-nonrelated adverse events were recorded. In Trulene® mesh group, fever (5%), fever with fatigue (1.67%), cough with fever (1.67%), cold and cough (1.67%), fever and nausea (3.33%), nausea (1.67%), nausea/vomiting (1.67%), weakness and fatigue (1.67%), headache (3.33%), constipation (5.00%), general body pains (1.67%), serous discharge (1.67%), parasitic infection (1.67%), and COVID-19 infection (1.67%) were recorded. In Prolene® mesh group, hypertension (1.67%), cold and cough (1.67%), upper respiratory tract infection (1.67%), fever (13.33%), diarrhea (1.67%), diarrhea and weakness (1.67%), scrotal edema (1.67%), inflammatory response (1.67%), serous discharge (1.67%), and

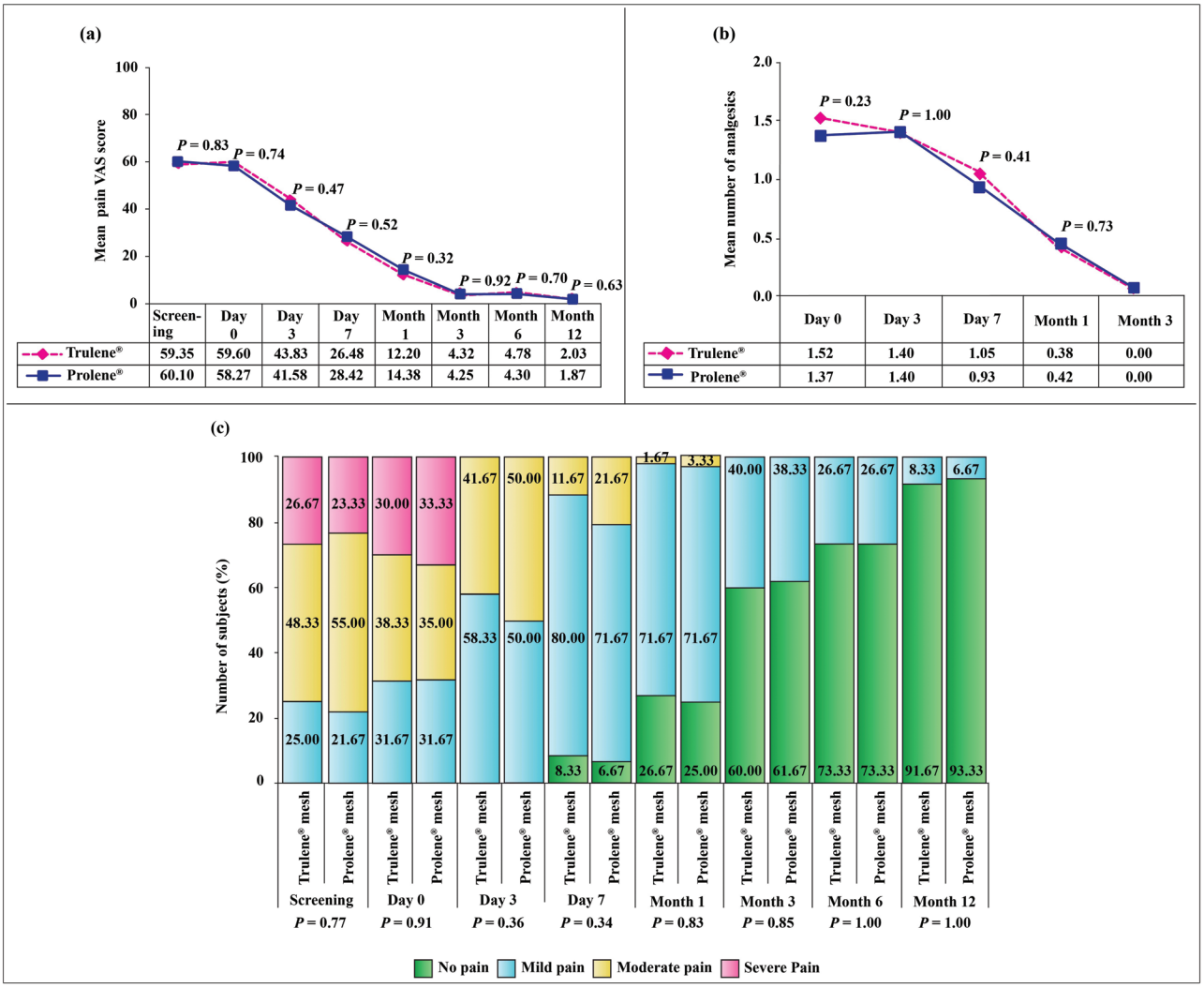

Figure 3: Graphical representation of (a) pain VAS score, (b) number of analgesics, and (c) postoperative pain intensity [Trulene® mesh (*n* = 60) and Prolene® mesh (*n* = 60) group]

prostatomegaly (1.67%) were noted. Details of mostly used prescribed medications are summarized in Table 4.

Discussion

Across the world, more than 20 million people undergo groin hernia repair yearly, of whom 10%–15% develop recurrence and require resurgery, while 10%–12% suffer from chronic (≥3 months) postoperative pain.[5] Clinical effectiveness of hernia repair depends on low recurrence rate, pain and postoperative complications, and short hospital stay and recovery time.[13] The common and safe method of Lichtenstein open repair with mesh fixation lowers the rate of recurrence, complication, and morbidity.[7] This study compared the clinical equivalence of Trulene® and Prolene® polypropylene mesh for Lichtenstein open repair of primary IH based on recurrence rate, 6- and 12-month postsurgery.

Both groups were comparable with respect to demographic and clinical variables, except history of alcohol consumption. However, the primary outcome of this study was not influenced by this heterogeneity, as the hernia recurrence rate was nil in both Trulene® and Prolene® mesh groups. The HerniaSurge Group guidelines[5] also suggested lower recurrence rate with mesh-based techniques, compared to nonmesh techniques. On the contrary, other studies reported 47.1% and 49.4% recurrence of indirect and direct IHs, respectively, with highest (17.25%) noted within 1 year of surgery,[14] and 5.4% recurrence within 12–70 months following open sublay repair.[15] An Indian study recorded 38.1% and 61.7% recurrence within and after 2 years of primary repair, respectively.[16] Similar to our findings, a previous Indian comparative randomized study found no recurrence following Lichtenstein's tension-free mesh hernioplasty.[17]

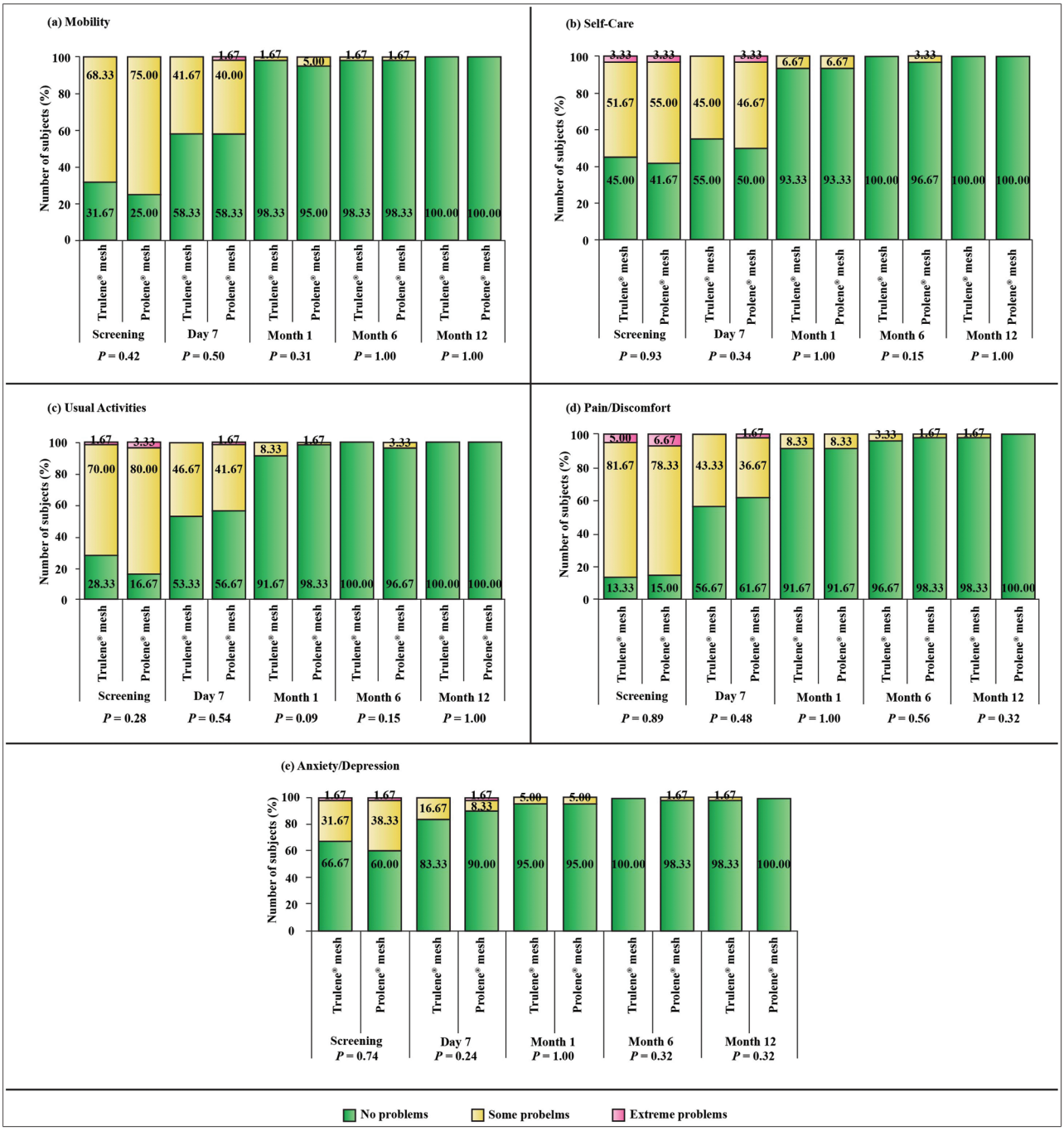

Figure 4: Graphical representation of quality of life with respect to (a) mobility, (b) self-care, (c) usual activities, (d) pain/discomfort, and (e) anxiety/depression [Trulene® mesh (*n* = 60) and Prolene® mesh (*n* = 60) group]

The HerniaSurge Group guidelines[5] have indicated similar risk of postoperative pain with both mesh and nonmesh-based techniques. Significantly greater pain and 45% analgesic requirement after mesh fixation with polypropylene sutures than mesh fixation with cyanoacrylate glue were reported.[10] Chronic pain in 13.6% subjects at 4 months of surgery was observed that reduced to 4.0% after 2 years.[18] A likely reduction of severe postoperative pain with each consecutive visit was also noted in both groups of this study. As a result, the requirement of analgesic was gradually decreased, and in both groups, no requirement was recorded from Month 3 onward.

A meta-analysis reported more incidents of wound infection, seromas, and wound swelling with mesh repair of IH than nonmesh repair, whereas higher events of wound dehiscence were recorded with nonmesh repair.[8] Another study found 2.9% hematoma, 22.9% seroma,

and 5.7% infection following Lichtenstein mesh repair.[17] In this study, only one subject of Trulene® mesh group experienced seroma on Day 3 and one subject of Prolene® mesh group developed dehiscence on Day 7; otherwise, there were no recorded incidents of hematoma, swelling, and infection in both groups. Therefore, the lower rate of postoperative complications along with gradually decreasing pain indicated proficiency of polypropylene mesh in fast recovery following Lichtenstein open repair of primary IH. In addition, no incidence of hernia recurrence eliminated the chance of resurgery, hence reduced the patient morbidity and health-care costs.

An ideal mesh must have tensile strength and capability to mimic the elasticity of abdominal wall to accelerate healing process. Proper mesh fixation reduces 5% postsurgery recurrence rate.[1] The intraoperative mesh parameters of this study showed similar results between the groups. More "Excellent" scores regarding fixation preciseness and memory of Trulene® mesh, and fixation quality, manipulability/comfort in use, stretch capacity or flexibility, and abdominal wall compliance of Prolene® mesh were recorded. In addition, more "very good" scores were marked for fixation quality, manipulability/comfort in use, stretch capacity or flexibility, memory and abdominal wall compliance of Trulene® mesh, and fixation preciseness of Prolene® mesh. Moreover, the recorded adverse events in both groups were not related to the mesh materials used in this trial.

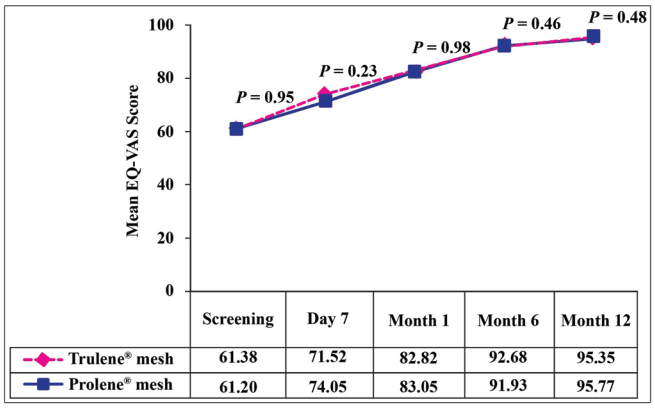

Figure 5: Graphical representation of changes in mean EQ-VAS score [Trulene® mesh (n = 60) and Prolene® mesh (n = 60) group]

The EQ-5D is a standardized preference-based measure of health that provides a simple, generic measure for health-related assessment.[19] In the analysis of each QOL dimension of this study, the proportion of no problems for each dimension was increased with every follow-up, starting from Day 7. In addition, the analysis of respondents' subjective health perception by EQ-VAS score revealed an intragroup improvement in health in both Trulene® and Prolene® mesh groups. Furthermore, the comparable time of hospital stay, and return to day-to-day activities and work, suggested similar recovery in both groups.

The rigorous and intensive analysis of this study's outcomes validated the clinical use of Trulene® polypropylene mesh in much wider population. Trulene® polypropylene mesh can be used in all surgeries indicated for Prolene® polypropylene mesh. Limitation of this study is that the surgeons were not blinded; hence, potential bias may have occurred during the intraoperative mesh handling, in favoring one mesh over another.

Therefore, the nonsignificant difference between Trulene® polypropylene mesh and Prolene® polypropylene mesh groups regarding the primary and secondary endpoints indicated clinical equivalence of two meshes. Furthermore, both Trulene® polypropylene mesh and Prolene® polypropylene mesh are safe and effective for Lichtenstein open repair of primary IH with minimal risk of hernia recurrence and chronic pain.

Table 4: Concomitant or prescribed medications

Prescribed medications	Trulene® mesh (n = 60)	Prolene® mesh (n = 60)
Analgesics		
Paracetamol, n (%)	48 (80.00)	46 (76.67)
Diclofenac, n (%)	32 (53.33)	35 (58.33)
Tramadol, n (%)	15 (25.00)	23 (38.33)
Tramadol + acetaminophen, n (%)	15 (25.00)	14 (23.33)
Ibuprofen + paracetamol, n (%)	14 (23.33)	14 (23.33)
Antibiotics		
Ceftriaxone, n (%)	24 (40.01)	28 (46.67)
Amoxicillin, n (%)	20 (33.33)	19 (31.67)
Clavulanic acid, n (%)	18 (30.00)	17 (28.33)
Cefoperazone + sulbactam, n (%)	19 (31.67)	15 (25.00)
Cefuroxime, n (%)	14 (23.33)	14 (23.33)
Amikacin, n (%)	13 (21.67)	13 (21.67)
Gastrointestinal		
Pantoprazole, n (%)	55 (91.67)	55 (91.67)
Ondansetron, n (%)	27 (45.00)	21 (35.00)

Registration number

This trial is registered prospectively at the Clinical Trial Registry of India (CTRI Reg. No.: CTRI/2020/02/023307; registered on: 13/02/2020). URL: https://ctri.nic.in/Clinicaltrials/showallp.php?mid1=38976&EncHid=&userName=trulene%20polypropylene%20mesh

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Authors' contributions

Concept: V.H., N.B.T., S.B.M., N.A., A.K.M., D.T.S.
Design: V.H., N.B.T., S.B.M., N.A., A.K.M., D.T.S.
Definition of intellectual content: V.H., N.B.T., S.B.M., N.A., A.K.M., D.T.S.
Literature search: V.H., N.B.T., S.B.M., N.A., A.K.M., D.T.S.
Clinical studies: V.H., N.B.T., S.B.M., N.A.
Experimental studies: V.H., N.B.T., S.B.M., N.A.
Data acquisition: V.H., N.B.T., S.B.M., N.A., A.K.M., D.T.S.
Data analysis: V.H., N.B.T., S.B.M., N.A., A.K.M., D.T.S.
Statistical analysis: V.H., N.B.T., S.B.M., N.A., A.K.M., D.T.S.
Manuscript preparation: V.H., N.B.T., S.B.M., N.A., A.K.M., D.T.S.
Manuscript editing: V.H., N.B.T., S.B.M., N.A., A.K.M., D.T.S.
Manuscript review: V.H., N.B.T., S.B.M., N.A., A.K.M., D.T.S.
Guarantor: Deepak T.S. takes responsibility for the integrity of the work as a whole from inception to the published article.

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Conflicts of interest

A.K.M. and D.T.S. work for Healthium Medtech Limited, which manufactures Trulene® mesh. V.H., N.B.T., S.B.M., and N.A. report no conflicts of interest in this work.

References

1. See CW, Kim T, Zhu D. Hernia mesh and hernia repair: A review. Eng Regen 2020;1:19-33.
2. Pandya B, Huda T, Gupta D, Mehra B, Narang R. Abdominal wall hernias: An epidemiological profile and surgical experience from a Rural Medical College in Central India. Surg J 2021;07:e41-6.
3. Köckerling F, Simons MP. Current concepts of inguinal hernia repair. Visc Med 2018;34:145-50.
4. Chendjou WT, Christie A, Carvalho M, Nana T, Wepngong E, Dickson D, *et al*. The prevalence and characteristics of untreated hernias in Southwest Cameroon. J Surg Res 2019;244:181-8.
5. The HerniaSurge Group. International guidelines for groin hernia management. Hernia 2018;22:1-165.
6. Mcbee PJ, Walters RW, Fitzgibbons RJ. Current status of inguinal hernia management: A review. Int J Abdom Wall Hernia Surg 2022;5:159-64.
7. Guttadauro A. Techniques and Innovation in Hernia Surgery. IntechOpen; 2020. Available from: https://www.perlego.com/book/2026717/techniques-and-innovation-in-hernia-surgery-pdf.
8. Lockhart K, Dunn D, Teo S, Ng JY, Dhillon M, Teo E, *et al*. Mesh versus non-mesh for inguinal and femoral hernia repair. Cochrane Database Syst Rev 9:CD011517.
9. Tabiri S, Owusu F, Atindaana Abantanga F, Moten A, Nepogodiev D, Omar O, *et al*. Mesh versus suture repair of primary inguinal hernia in Ghana. BJS Open 2019;3:629-33.
10. Fouda E, Thabet W, Elsaid M, Emile S, Elbaz S. A randomized clinical trial of mesh fixation with cyanoacrylate glue compared to sutures in inguinal hernia repair. Int J Abdom Wall Hernia Surg 2020;3:56.
11. Bury K, Śmietański M, Bury K. Five-year results of a randomized clinical trial comparing a polypropylene mesh with a poliglecaprone and polypropylene composite mesh for inguinal hernioplasty. Hernia 2012;16:549-53.
12. Srinivas NM, Devaprashanth M. Lichtenstein mesh hernioplasty: The extreme refinement in hernia surgery. Int Surg J 2018;5:87-91.
13. Techapongsatorn S, Tansawet A, Kasetsermwiriya W, Pattanaprateep O, Thakkinstian A. Mesh fixation technique for inguinal hernia repair: Protocol for an umbrella review with integrated and updated network meta-analysis. BMJ Open 2019;9:e0317421-5.
14. Lee CS, Kim JH, Choi BJ, Lee JI, Lee SC, Lee YS, *et al*. Retrospective study on prevalence of recurrent IH: A large-scale multi-institutional study. Ann Surg Treat Res 2020;98:51-5.
15. Chen F, Nie Y, Guo Y, Bittner R, Yang H, Chen J. Outcomes of recurrent incisional hernia repair with different mesh repair approach: A retrospective cohort study in a single institution. Research Square 2022. DOI: 10.21203/rs.3.rs-1711844/v1.
16. Bansal P, Mongia A. A retrospective study on prevalence of recurrent and primary inguinal hernia in a tertiary care teaching hospital. Int J Med Res Prof 2017;3:408-10.
17. Naveen N, Srinath R. A comparative study between modified Bassini's repair and Lichtenstein mesh repair (LMR) of inguinal hernias in rural population. J Clin Diagn Res 2014;8:88-91.
18. Bande D, Moltó L, Pereira JA, Montes A. Chronic pain after groin hernia repair: pain characteristics and impact on quality of life. BMC Surg 2020;20:1-11.
19. Emrani Z, Sari AA, Zeraati H, Olyaeemanesh A, Daroudi R. Health-related quality of life measured using the EQ-5D–5L: Population norms for the capital of Iran. Health Qual Life Outcomes 2020;18:1-9.