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Efficacy and safety of NBCA (n-butyl-2-cyanoacrylate) medical adhesive for patch fixation in totally extraperitoneal prosthesis (TEP): a prospective, randomized, controlled trial

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Abstract. – OBJECTIVE: To evaluate the effectiveness of n-butyl-2-cyanoacrylate (NBCA) medical adhesive for mesh fixation in totally extraperitoneal prosthesis (TEP) for inguinal hernia repair.

PATIENTS AND METHODS: A total of 160 patients with primary unilateral inguinal hernia were assigned randomly to receive TEP using NBCA medical adhesive for patch fixation (experimental group) and without patch fixation (control group). We evaluated operation time, visual analogue scale (VAS) pain score 24 h after surgery, postoperative duration of stay, hospital costs, postoperative complications, and hernia recurrence.

RESULTS: A total of 160 cases were operated successfully. There was no significant difference in operation time, VAS pain score 24h after surgery, postoperative duration of stay, hospital costs and postoperative complications between the groups ($p > 0.05$). Hernia recurrence occurred in 4 cases of the control group. None of the experimental group had a significant difference ($p < 0.05$).

CONCLUSIONS: The use of NBCA medical adhesive for patch fixation in TEP is effective and safe.

Key Words:
Inguinal hernia, Laparoscopic hernia repair, TEP, Medical adhesive, NBCA (n-butyl-2-cyanoacrylate), Mash fixation.

Introduction

An inguinal hernia is one of the most common diseases in general surgery. Lichtenstein opened the new tension-free repair era when he implanted a marlex mesh instead of the traditional tension repair in 1989[1,2]. From then on, tension-free hernia repair using the artificial material for the treatment of an inguinal hernia had been recognized as the gold standard because of its low recurrence rate and high comfortable degree[2-4]. On the basis of the above technique, surgeons had gradually developed a minimal invasive laparoscopic approach which seems to have faster recovery, lower recurrence rate, less postoperative chronic pain and better quality of life[5-8]. However, the methods of mesh fixation or not for laparoscopic inguinal hernia repair has been disputed by several surgeons who are associated with recurrence rate, risk for chronic pain and local foreign body sensation[9,10]. So the role of the fixation of the mesh is especially important regarding the endoscopic technique. Although the approach of fixing the mesh patch with non-absorbable titanium spiral tacks which could reduce recurrence rate has been widely used for many years, it has several disadvantages, including the increased incidence of postoperative pain, long-term chronic pain, local foreign body sensation and even bowel lesion[11,12].

To improve postoperative life quality of patients, medical adhesive mesh fixation including chemical adhesives and biological adhesives which are less invasive patch fixation methods emerged and got satisfactory effects[13,14]. In our institution, we tend to use chemical glues because of the feature of high adhesive strength which biological glues lacked. Chemical glues can reach an adhesive strength of up to 11 N/cm^2 (equivalent to 825 mmHg or 1,122 cm H_2O).

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Table I. Patient characteristics.

	Group		
	Experimental (n = 80)	Control (n = 80)	*p*-value
Age (years)	55.9 ±14.6	60.0 ± 13.5	.982
22.5 Male (%)	56 (70.0)	65 (81.2)	.097
BMI (kg/m2)	22.3 ± 2.1	22.1 ± 2.3	.597
Maximum hernia diameter(cm)	3.4 ± 0.5	3.4 ± 0.5	.798
Type of hernia			.807
Direct (%)	9 (11.2)	10 (12.5)	
Indirect (%)	71 (88.8)	70 (87.5)	
Cerebral or cardiovascular disease (%)	23 (28.8)	18 (22.5)	.365
Diabetes mellitus (%)	15 (18.8)	10 (12.5)	.276
Other diseases related to increased IAP (%)	19 (23.8)	14 (17.5)	.329
Preoperative VAS score	0.8 ± 0.5	0.9 ± 0.5	.282

Data are presented as mean ± standard deviation (SD) for continuous variables and number (%) for categorical variables.

Normal intra-abdominal pressure (IAP) usually fluctuates from 12 to 25 mm Hg and the transversalis fascia has to resist this high pressure[15-19]. Theoretically, chemical glues provide higher adhesive strength than the pressure placed on the transversalis fascia and can attach the mesh patch firmly onto the transversalis fascia defect (the hernia ring). While some other surgeons advocate no mesh fixation in order to minimize the risk of post-surgical discomfort and save hospital costs[20,21].

We conducted this prospective, randomized, controlled study from July 2013 to July 2014 using a lightweight polypropylene mesh for TEP to assess the effectiveness and safety of chemical adhesive patch fixation in comparison with no mesh fixation.

Patients and Methods

This study was approved by the Ethical Review Board of the Capital Medical University-Affiliated Beijing Chao-Yang Hospital, and all procedures were performed in accordance with Good Clinical Practice guidelines and Chinese

Table II. Surgical and follow-up data.

	Group		
	Experimental (n = 80)	Control group (n = 80)	*p*-value
Operation time (min)	30.4±3.9	29.7 ± 3.6	.263
VAS pain score 24h after surgery	2.0±0.3	2.0 ± 0.3	.110
Postoperative duration of stay (days)	1.8±0.8	1.7 ±0.7	.344
Hospital costs* (RMB)	9057.2±130.4	8824.7±126.5	.000
Complications			
Chronic pain[a]	0	0	-
Seroma (%)			
Other complications	14 (17.5)		
0	13 (16.2)		
0	.833		-
Hernia recurrence (%)	0 (0)	4 (5.0)	.043

Data are presented as mean ± standard deviation (SD) for continuous variables and number (%) for categorical variables.
VAS visual analogue scale.
p-values were calculated by independent t-test for continuous variables and chi-square test or Fisher's exact tests for categorical variables.
Indicates statistical significance, $p < 0.05$.
*Hospital costs include inspection fees, surgical fees, anesthesia fees, equipment use costs.
[a]VAS ≥ 4

regulations. All participants provided informed consent for inclusion in the study and surgical procedures performed.

Participants

160 cases of inguinal hernia patients who fit the inclusion and exclusion criteria were assigned to either the experimental group or control group by a computerized randomization process and received hernia repair at the Hernia and Abdominal Wall Surgery department of Beijing Chao-Yang Hospital, Capital Medical University, between July 2013 and July 2014. All patients were blinded to the allocation. They were enrolled if they met the inclusion criteria, including: 1) clinical diagnosis of primary unilateral inguinal hernia; 2) age >18 years; and 3) no significant cardiopulmonary, hepatic, or renal impairment, and no contraindications for surgery. Exclusion criteria included: 1)bilateral inguinal hernia, recurrent hernia, and incarcerated hernia; 2) allergy to multiple classes of drugs, recent allergic disease, or use of drugs that are known harmful to vital organs during the 4 weeks before surgery; 3) participation in other clinical studies in the 3 months before surgery; 4) atopic allergy history; 5) mental illness history; 6) disease that may significantly increase IAP and cannot be effectively controlled, such as severe ascites, severe asthma caused by bronchitis, pulmonary emphysema, or urine retention caused by significant benign prostatic hyperplasia (BPH); and 7) infection located at the surgical site or bacteremia. Males and females were considered for inclusion.

Surgical Procedure

The patients were under general anesthesia during the entire surgery. A 2-cm longitudinal infraumbilical skin incision was made, dissection was carried down to identify the anterior rectus sheath and expose the preperitoneal space. Inserted a 10-mm laparoscope through this port and connected to the CO_2 supply to let the preperitoneal space distend. Two working 5-mm ports were inserted below the 10-mm port in the midline. The hernia sac was then visualized, identified as direct or indirect, and reduced. Then a lightweight polypropylene mesh (Covidien, Mansfield, MA, USA) was routinely used for its convenient properties, and the mesh size measured at least 10 cm × 15 cm. The patch must be large enough to extend 5 cm beyond the exterior margin of inner ring. The mesh was secured to the abdominal wall by NBCA fixation in experimental group and no fixation in control group. NBCA fixation was performed as follows. The glue application set (Compont Medical Adhesive, 1.5 ml/tube; Beijing Compont Medical Devices Co., Ltd., Beijing, China) consists of a sprayer, catheter, and NBCA glue. The catheter is introduced through one of the operating trocars, and a 5 mm grasper is introduced through a third trocar to assist in directing the application of the glue. The glue is sprayed on the mesh, which is then pressed gently against the underlying tissue. The glued spots should be as small as possible, as tissue ingrowth in these areas is limited until the glue degrades. Exsufflation is done under direct vision and any trocar incision larger than 5 mm is closed in layers with absorbable surgical suture.

Outcome Measures

The main outcome measures were the operation time, VAS pain score 24 hours after surgery, postoperative duration of stay, hospital costs, and postoperative complications including wound infection, local hematoma formation, seroma, chronic pain, and whether there was hernia recurrence. VAS pain score was determined based on a scale of 0-10 with 0 equal to no pain and 10 equal to the worse pain imaginable. Outpatient follow-up was performed at 1, 3, 6 and 12 months after operation. Chronic pain was defined as moderate or greater pain in the inguinal area 3 months after surgery in which the VAS pain score was ≥4.

Statistical Analysis

To detect the differences between the control and experimental groups, a sample size of 36 patients per group was required. This was determined using the *Z*-test for population proportion with an α value of 5% and power defined as 80%. The hypothesis is that at the end of the study, the mean difference in recurrent rate between the 2 groups was no more than 15%. After taking a dropout rate of 30% to 40% into account, 160 subjects were needed for the study. Descriptive statistical analysis was performed with SPSS, version 17.0 (SPSS Inc., Chicago, IL, USA) statistical software. Continuous variables are presented as the mean ± standard deviation (SD) and independent t-test test was used to examine the differences between each group. The C^2 test was used for categorical variables. When 20% of cells had an expected value <5, the Fisher exact test was used instead. $p<.05$ was statistically significant.

Results

Of 1025 patients with inguinal hernias who were seen at our department between July 2013 and July 2014, 160 met the inclusion and exclusion criteria and were enrolled in our study. Data for all 160 patients were included in the analysis, and the baseline characteristics are shown in Table I. No significant differences in age, gender, BMI, maximum diameter of the hernia ring, the distribution of hernia type, underlying chronic disease history and preoperative VAS score were found between the control group and experimental group and they are comparable.

Surgical and follow-up data are shown in Table II. The main outcome measures were the operation time, VAS pain score 24h after surgery, postoperative duration to stay, hospital costs and complications. Complications include chronic pain, seroma, recurrence and some other situations. There was no significant difference in operation time (30.4±3.9 min *vs.* 29.7 ± 3.6 min, respectively; $p = 0.263$), VAS pain score 24h after surgery (2.0±0.3 *vs.* 2.0±0.3, respectively; $p = 0.110$) and postoperative duration to stay (1.8±0.8 days *vs.* 1.7 ±0. 7 days, respectively; $p = 0.344$) between these two groups. All the patients were followed for 12 months and no one was lost to follow-up. At the final follow-up, no chronic pain and other complications such as wound infections had occurred in both of the groups, while 14 cases (17.5%) of seroma were noted in the experimental group and 13 cases (16.2%) in the control group without significant difference ($p = 0.833$).

Hernia recurrence was occurred in 4 cases (5.0%) of the control group at 6 months after operation and none of the experimental group with significant difference ($p = 0.043$), however, all the recurrence cases were undergoing reoperation.

Hospital costs were significantly lower in the control group with no fixation than in the experimental groups with NBCA fixation (8824.7±126.5 RMB *vs.* 9057.2±130.4 RMB, respectively; $p < 0.05$). But when we made the follow-up, we asked for patients' opinions that they could accept the overall hospital costs and negligible difference of hospital fees.

BMI body mass index, IAP intra-abdominal pressure, VAS visual analogue scale.

p-values were calculated by independent *t*-test for continuous variables and chi-square test or Fisher's exact tests for categorical variables.

Indicates statistical significance, $p < 0.05$.

Discussion

The current prospective, randomized, controlled trial compared the NBCA medical adhesive for mesh fixation versus non-fixation for primary inguinal hernia repair according to laparoscopic TEP[22]. The results showed that these two fixation methods didn't exhibit significant statistical difference in terms of operation time, postoperative duration of stay, hospital costs and VAS pain score 24h after surgery. However, medical adhesive fixation showed advantage in hernia recurrence rate over no mesh fixation and no other postoperative complications occurred with either method.

To appraise the effect of repair for an inguinal hernia comprehensively, two evaluating indexes are obliged to be referred, postoperative comfort degree and recurrence rate. In recent years, with further study on the anatomy of the groin and the improvement of surgical technique, recurrence rate of an inguinal hernia has been greatly reduced. Comfort degree for patients after surgery gradually turn into a focus in the field of hernia surgery. For laparoscopic hernioplasty, both TAPP and TEP, the method of mesh fixation is considered as a crucial factor which affects the patients' postoperative quality of life. To follow this trend, adhesive fixation as a less invasive patch fixation method is becoming popular, because it reduces the risk of postoperative complications, such as chronic pain and improves patients' quality of life.

Cyanoacrylates (CA) are a group of adhesives, and if they contact a liquid or basic substance, an exothermic reaction can be motivated to make them polymerize and form a strong bond. Owing to this feature, butyl-2-CA, NBCA, 2-octyl CA and so forth are developed as tissue adhesives and used widely in surgical applications nowadays, such as transcatheter arterial embolization for urgent control of acute arterial bleeding, cystoscopic injection into the anastomotic gap and repairing lacerations of parenchymal organs and dermal tissue[23-27]. With the advantage of fast acting and powerful adhesive strength, Compont, an NBCA chemical adhesive, is the only surgical adhesive used in China today, which can be not only used on the surface of skin but also in the abdominal cavity[28].

However, in recent years, a part of surgeons advocate that TEP isn't necessary to fix the mesh by any methods of mesh fixation in order to minimize the risk of post-surgical discomfort

and save hospital costs[20-21,29]. But this may lead to early mesh displacement, mesh folding or mesh shrinkage, which may not only cause hernia recurrence but also chronic pain and sometimes severer complication such as injury of vas deferens, femoral vessels, bowel, and bladder. This makes patients' postoperative quality of life decline notably. Many surgeons have reported that the type of mesh and the method of mesh fixation are crucial factors to mesh migration and erosion[30,31]. To ensure long-term repair efficiency and prevent from a hernia recurring and serious injury, appropriate fixation method should be retained[32].

In our study, the findings revealed that a higher recurrence rate occurred in the control group compared with experimental group, which demonstrate the necessity of medical adhesive in laparoscopic TEP for inguinal hernia repair. The immediate cause of recurrence, or one of the causes, appears to the patch dislocation by intraoperative findings when performed reoperation. In general, medical adhesives can completely degrade in 3-9 months, which provides sufficient time to maintain strong fixation of the mesh until biologic ingrowth occurs. The application of medical glue may prolong operative time and increase hospital cost relatively, but these differences are not statistically significant. Meanwhile, safety and effectiveness of TEP are ensured exactly. In our institution, it was lucky that displacement of mesh didn't lead to erosion of bowel, bladder, and some other vital structures, but may cause serious consequences once they happen.

These two methods of mesh fixation had no difference in postoperative chronic pain, local hematoma, seroma and some other complications in our study. Availably and reliably hemostatic effect of medical adhesives which could prevent and reduce hematoma and seroma following surgeries has been reported by some surgeons[33], but we could not discover this advantage. Also, the medical adhesives are a temporary and degradable foreign body that does not compress nerves and penetrate tissues. Thus, no patient with pain appeared, either acute pain or long-term chronic pain.

The study is limited in that it was performed at a single center and might not reflect other institutions' practices. Furthermore, it was performed without a sufficient long-term follow-up and large sample size. Most hernia studies suggest that the follow-up of inguinal hernia repair should continue to 5 years after surgery[34]. However, for the purpose of evaluating the method of mesh fixation, 1-year follow-up is sufficient in theory because long-term hernia recurrence (over 6 months) is related more to a patient's physical condition and factors such as increased intra-abdominal pressure, abnormalities of collagen metabolism and smoking[15]. There had been reported that some patients had inguinal pulling and burning sensations after the use of medical adhesive[35], but it never had been found in our institution. So further research is required to investigate in larger sample size, longer-term and multicentric studies.

Conclusions

The results of our study showed that the use of NBCA medical adhesive for patch fixation in TEP for inguinal hernia repair is effective and safe. The application of NBCA a medical adhesive for mesh fixation offers a significant advantage in postoperative recurrence rate compared to no fixation, and there is no difference in the other clinical outcomes between these two groups. The slight increase in hospital costs which has no statistical significance is balanced by a relatively safe repairing effect.

Conflict of interest

The authors declare no conflicts of interest.

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