

Original Article

Development and application of scrotum belt in patients with hydrocele

Fei Wang, Chuanyi Hu, Guozeng Wang

Department of Urology, Gongli Hospital Affiliated to The Second Military Medical University, Shanghai, China

Received November 18, 2016; Accepted June 20, 2017; Epub August 15, 2017; Published August 30, 2017

Abstract: Objective: To develop a scrotum belt for supportive care of patients with hydrocele, and to evaluate its application in a clinical trial. Methods: A scrotum belt was developed based on a comprehensive literature review and expert consultations. Sixty patients who underwent surgery for hydrocele were randomly divided into experimental and control groups (N=30 for both). Patients in the experimental group used the scrotum belt and those in the control group used sandbag to elevate the scrotum. The regression of hydrocele and the degree of comfort experienced by patients in the two groups were compared. Results: One week after the operation, the average size of scrotum in the experimental group was significantly smaller than that in the control group (22.5 ± 1.24 cm and 23.55 ± 0.89 cm, respectively, $t = -3.75$, $P < 0.01$). In the experimental group, the use of scrotum belt was rated as markedly effective or effective in 25 (83.3%) of patients, in accordance to the standard criteria for classification of curative effect. In the control group, the curative effect was rated as ineffective in 15 (50%) patients. The comfort score in the experimental group was significantly higher than that in the control group ($t = 9.774$, $P < 0.01$). Conclusion: The scrotum belt designed and tested as part of this study promoted postoperative regression of scrotum after surgery for hydrocele, and improved comfort level of patients. Use of the belt in clinical settings could benefit patients with hydrocele.

Keywords: Hydrocele, scrotum belt

Introduction

Hydrocele refers to accumulation of clear fluid in the tunica vaginalis, which is a common condition characterized by painless enlargement of the scrotum on the affected side. Systemic and local causes of scrotal edema include filariasis, cirrhosis of the liver, epididymitis, post-varicocelelectomy, testis hydrocele of tunica vaginalis, and epididymal or scrotal masses [1-4], which contribute to its high incidence.

Hydrocele typically develops in adulthood, particularly in the elderly population in countries with a hot climate. For example, 283 out of 1731 Brazilian men aged ≥ 40 years who underwent screening for prostate cancer were found to have hydrocele [5]. The prevalence of hydrocele in China is relatively low. In a study conducted between 1984 and 1988 across 252 villages in China, 298 out of a total of 1,038 patients with filariasis were found to have hydrocele [6]. In a survey of 5172 randomly sampled male adolescents in China, the preva-

lence rate of hydrocele was found to be 0.87% [7]. Despite the relatively low disease burden of hydrocele in China, the condition still merits our attention due to the large population base and the suffering associated with hydrocele.

Most hydroceles that appear in the first year of life tend to resolve spontaneously in the absence of any treatment. However, surgical intervention is required for hydroceles that persist after the first year, and for those that occur later in life. Although surgical treatment is effective and is associated with satisfactory long-term results [8], it may cause complications, such as scrotal hematoma, edema, and wound infection, due to the abundant blood supply and distensibility of the scrotal sac.

Therefore, appropriate supportive care for relief of edema and pain is an important element in the management of these patients. The traditional nursing measures for relief of scrotal edema have included use of cotton, sandbag or clothing beneath the scrotum, so as to lift the



Figure 1. The partly display of the belt. Due to its novel design and clinical application, the manufactured scrotum belt has received a Patent Certificate of a New and Practical Model issued by the state intellectual property office.

scrotum and promote circulation of blood and lymph, and to alleviate the local swelling and pain. However, due diligence is required for this measure as inappropriate use may affect heat dissipation, raise local temperature, aggravate patient discomfort and delay recovery.

In order to reduce the risk of complications, to shorten the length of hospital stay, and to improve patient satisfaction, we developed a scrotum belt based on a review of literature and expert opinion and tested the same in a clinical setting.

Materials and methods

Research group

A multi-disciplinary R&D team which comprised of the chief physician of Urology, a stomal therapist, 2 specialist nurses, 2 senior nurses, 1 development engineer, and a urology care expert were invited.

Development of the scrotum belt

A comprehensive review of articles published over the past decade was performed on Wanfang, CNKI and Pubmed databases and the evidence collated and analyzed. Subsequent to this, a brainstorming session was conducted in which nine clinical nurses with more than 3 years of experience, each, in urology, envisaged practical problems encountered during nursing care and compiled them on a piece of paper. Later, all members of the team dis-

cussed and designed a prototype scrotum belt based on the preliminary data collected and the outcomes of the brainstorming sessions. The prototype of the belt was designed after discussions, analysis, and evaluation, on the basis of previous research.

The scrotum belt was modified four times by the research group, and eventually a prototype scrotum holder was designed with due consideration of the practical aspects of its use and safety. The material of scrotum belt was biocompatible, soft, safe, convenient to use, and adhered to the principles of mechanics.

Production and application of scrotum belt

We contacted a specialized medical material manufacturer to produce the scrotum belt. The belt comprised of one main belt and four fixing bands at the four corners of the main belt. The width of the main belt was 12-15 cm, and the length was ≥ 20 cm; the main belt with the back button is provided at the four corners; fixing bands were used as retractable elastic belts (length ≥ 60 cm, width ≥ 5 cm), which had a button hole at its end. The scrotum belt was adjustable according to the thigh circumference. The thighs provide fixed support for the scrotum, which serves to prop up the scrotum naturally. Due to patent restrictions in China, the design of the belt is not fully displayed. The main raw material of the belt was cotton. A related picture is shown in **Figure 1**.

Clinical investigation

Sixty patients with hydrocele who visited Urology Department at the Gongli Hospital Affiliated to the Second Military Medical University, between November 2012 and June 2015, were eligible for inclusion in this study. Random number table was used to assign patients to the experimental or control group (N=30 for each).

Inclusion criteria

(1) Patients who underwent scrotal surgery for hydrocele of tunica vaginalis, epididymal cyst and prostate cancer during the study reference period; (2) Age >14 years; (3) Patients hospitalized for treatment; (4) Normal ability to communicate; (5) Written informed consent obtained from the patient.

Development of scrotum belt for hydrocele

Table 1. Regression of hydrocele by study group

Group	Mean (cm)	Std. Error	SD	t value	P
Experimental group	22.5	0.22	1.24	-3.75	<0.01
Control group	23.55	0.16	0.89		

SD, standard deviation.

Exclusion criteria

Patients with the following disorders were excluded: (1) Hypoproteinemia; (2) Scrotal tumor; (3) Tuberculosis; (4) Edema caused by acute scrotal skin infection; (5) Congenital disease.

Interventions

All subjects underwent surgical treatment for the underlying condition (vaginal resection or tumor resection). After surgery, scrotum belt was used by patients in the experimental group, while patients in the control group used a sand-bag to elevate the scrotum. Patients in both groups had access to a specially-assigned researcher to address any problems during the study, to periodically document the patient's condition and to conduct health education pertaining to the use of scrotum belt. This helped ensure proper compliance to treatment.

The chief complaints of the patient were recorded along with any changes in edema. In addition, the size of scrotum was measured with a tape and local signs were also recorded.

The participants were followed-up after discharge from the hospital and the regression of scrotal edema was assessed and recorded.

Degree of regression of hydrocele

Regression in the size of hydrocele was assessed one week after the operation. In order to ensure the accuracy of the evaluation, two researchers conducted the measurements independently, and the average value of the two measurements was recorded. The criteria used for evaluation were: resolution of local edema and restoration of scrotal size to normal at 1 week was considered markedly effective; reduction in the size of scrotum to more than half of the original size was considered as effective; scrotal size more than half of the immediate postoperative size was considered as ineffective.

Survey on degree of comfort

The degree of patient comfort after use of the scrotal belt was assessed by means of a questionnaire survey.

The questions pertained to general information and information on various

variables used in the Comfort Status Scale.

We used the simplified Comfort Status Scale (general comfort questionnaire, GCQ) developed by Kolcaba, which has been shown to have a good reliability (Cronbach's alpha =0.96) [9]. The content validity index (CVI) of the instrument is 0.86.

The scale has 30 items, which include five physiological items, ten psychological items, eight social and cultural items and seven environmental items. Each variable was scored by the participants using a Likert Scale (1-4 points); a score of 1 implied 'strongly agree' and a score of 4 implied 'strongly disagree'. The lowest possible total score was 30, while the highest possible score was 120. The higher the score, the higher was the comfort level as perceived by the patients. Between-group differences with respect to the degree of comfort were assessed three days after the operation.

Ethics statement

The study was funded by Health Science and Technology project of the Health and family planning commission, Pudong New Area, Shanghai (ID: PW2011A-8). The study was approved by the Ethics committee at the Gongli Hospital Affiliated to the Second Military Medical University. Written informed consent was obtained from all participants prior to their enrolment in the study.

Statistical methods

The non parametric Mann-Whitney test was used to assess the between-group differences with respect to qualitative data (assignment: ineffective =0, effective =1, markedly effective =2). Quantitative data are expressed as mean \pm standard deviation and the between-group differences were assessed using the independent sample *t* test. $P < 0.05$ was considered statistically significant. All analyses were performed with SPSS16.0 statistical software (IBM, United States).

Table 2. Regression of hydrocele by study group

Group	Markedly effective	Effective	Invalid	Total	Average rank	z value	P
Experimental group	7	18	5	30	37.25	-3.357	0.001
Control group	0	15	15	30	23.75		

Table 3. Comparison of the degree of patient comfort between the two groups

Group	N	Comfort score	Standard Error	SD	t value	P
Experimental group	30	89.73±11.8	2.16	11.8	9.774	<0.001
Control group	30	66.23±5.8	1.05	5.75		

SD, standard deviation.

Results

Basic information

Mean age of patients in the experimental and control groups was 61.3 years (range 41-79) and 59.5 years (range 31-79), respectively. There were no significant between-group differences with respect to age and education level ($P>0.05$). Preoperative size of the scrotum in the experimental and control groups was 27.95 ± 1.20 cm and 28.15 ± 1.08 cm, respectively. There was no significant between-group difference in this respect ($t=-3.7509$, $P=0.502$).

Degree of regression of hydrocele

One week after the operation, mean size of scrotum in the experimental and control groups was 22.5 ± 1.24 cm and 23.55 ± 0.89 cm, respectively; the between-group difference was statistically significant as assessed by *t* test (**Table 1**). Based on the criteria for classification of curative effect, use of scrotal belt was rated as either markedly effective or effective for 25 patients in the experimental group, which corresponded to an 83.3% curative effect. However, the curative effect was rated invalid in 25 patients (50%) in the control group. The between-group difference with respect to curative effect was statistically significant as assessed by the Mann Whitney test. The results indicate that scrotum belt effectively relieved scrotal edema associated with hydrocele (**Table 2**).

Degree of comfort

The GCQ scale was used to assess postoperative pain and activity level of the patient (3 days

after surgery) by the person responsible for administration of questionnaires. The comfort level of patients in the experimental group was significantly higher than that in the control group ($P<0.05$) (**Table 3**).

Discussion

Hydrocele has both physical and psychological impact on the afflicted individual [10, 11].

Concerns related to employment and marriage among young and middle-aged patients may induce depression, uncertainty about their future and affect their social well-being. In addition, elderly patients who have more conservative attitudes may not be willing to allow scrotal nursing care.

In clinical practice, nursing staff by virtue of their direct interaction with patients have a better understanding of the physiological and psychological needs of these patients. Therefore, inputs from nurses and clinicians can help improve appliances/aids. Furthermore, although the usual nursing aids such as cotton or sandbag have a certain effect on regression of hydrocele, these have their limitations and shortcomings. Therefore, nursing care appliances which can effectively reduce the hydrocele and alleviate patient discomfort, are a longstanding need of patients.

As compared to the other scrotal support devices, the scrotal belt used in this study was found to have some advantages. Firstly, the material used is soft, permeable to air and does not induce skin irritation. Secondly, the fixation of the belt is simple and effective; the main belt effectively secures the scrotum and prevents it from slipping out during movement or change in the position or posture of the body. Finally, it minimizes the risk of pressure ulcers. Severe swelling and inflammation of scrotum renders the scrotal skin more vulnerable. Therefore, elevation of scrotum helps improve blood circulation, hastens the resolution of edema and helps avoid complications.

The present study has some limitations. For example, information bias, as a result of imple-

mentation of different interventions may affect outcomes. However, we conducted a standardized training to minimize the effect of bias.

We found that compliance to treatment and the confidence of patients can be improved by taking cognizance of the psychological state of the patient and with appropriate psychological care. At the same time, use of this type of scrotum belt can promote regression of scrotum after surgery for hydrocele, and improve patient comfort, with a certain degree of social promotion and clinical application.

Acknowledgements

This work was supported by Key Medical Specialty Construction Project of Shanghai (Zk2015A11).

Disclosure of conflict of interest

None.

Address correspondence to: Chuanyi Hu, Department of Urology, Gongli Hospital Affiliated to The Second Military Medical University, 219 Miaopu Road, Shanghai 200135, China. Tel: +86-18918-156386; Fax: +86-21-68552018; E-mail: Huchuanyu2001@163.com

References

- [1] Cimador M, Castagnetti M and De Grazia E. Management of hydrocele in adolescent patients. *Nat Rev Urol* 2010; 7: 379-385.
- [2] Robinson JC, DeFranco JN and Hollowell CM. Malignant mesothelioma of the epididymis: a case report. *Curr Urol* 2014; 7: 217-218.
- [3] Yin Z, Yang JR, Wang Z, Wei YB, Yan B and Zhou KQ. Application of scrotoscope in the diagnosis and treatment of testicular and epididymal diseases. *Beijing Da Xue Xue Bao* 2015; 47: 648-652.
- [4] Soda T, Yamanaka K, Hirai T, Kishikawa H, Nishimura K and Ichikawa Y. A case of malignant peritoneal mesothelioma presenting with bilateral swelling of spermatic cord. *Hinyokika Kiyo* 2012; 58: 177-180.
- [5] Romero FR, Romero AW, Almeida RM, Oliveira FC Jr and Tambara Filho R. Prevalence and risk factors for scrotal lesions/anomalies in a cohort of Brazilian men ≥ 40 years of age. *Sao Paulo Med J* 2014; 132: 73-79.
- [6] Liang C, Wang K and Chen J. Epidemiological study of external genital diseases in 5172 adolescents. *Zhonghua Yi Xue Za Zhi* 1997; 77: 15-17.
- [7] Cui ZH, Liu B, Lin XJ, Gao CL, Tian GM, Wang DL, Zou ZS, Xie C, Shi JP, Song SF and et al. Epidemiological survey on patients with advanced filariasis in Shandong province with bancroftian filariasis basically eliminated. *Zhongguo Ji Sheng Chong Xue Yu Ji Sheng Chong Bing Za Zhi* 1990; 8: 245-248.
- [8] Yang XD, Wu Y, Xiang B, Wong K, Pei J and Li FY. Ten year experience of laparoscopic repair of pediatric hydrocele and the long-term follow-up results. *J Pediatr Surg* 2015; 50: 1987-1990.
- [9] Clemes MD, Ozanne LK and Laurensen WL. Patients' perceptions of service quality dimensions: an empirical examination of health care in New Zealand. *Health Mark Q* 2001; 19: 3-22.
- [10] Adhikari RK, Sherchand JB, Mishra SR, Rana-bhat K, Pokharel A, Devkota P, Mishra D, Ghimire YC, Gelal K, Paudel R and Wagle RR. Health-seeking behaviors and self-care practices of people with filarial lymphoedema in Nepal: a qualitative study. *J Trop Med* 2015; 2015: 260359.
- [11] Sachwitz D, Hass HJ, Kroker S, Meyer F and Krause H. Acute scrotum in childhood. *Zentralbl Chir* 2014; 139: 621-626.