

## A PROSPECTIVE RANDOMIZED TRIAL OF DRESSINGS VERSUS NO DRESSINGS FOR HYPOSPADIAS REPAIR

JOHN G. VAN SAVAGE, LUCIO G. PALANCA AND BRUCE L. SLAUGHENHOUP

*From the Division of Pediatric Urology, Department of Surgery, University of Louisville School of Medicine, Louisville, Kentucky*

### ABSTRACT

**Purpose:** Dressings following hypospadias repair have the benefits of gentle compression for hemostasis, immobilization of the wound and formation of a "hermetic seal." Potential disadvantages include producing ischemia, infection and pain during dressing removal. We compare the success and complications of hypospadias repair with and without dressings in a prospective randomized manner.

**Materials and Methods:** Children with hypospadias were randomized either to receive or not receive a transparent film dressing for 2 days. A written informed consent was obtained. Hypospadias repair was performed in 100 consecutive patients. Study exclusion criteria were known coagulopathy and oozing at the end of the case. Criteria for success were a glanular meatus, single forward directed stream, unimpeded voiding, absence of penile chordee, good cosmesis and no need for any secondary procedure. All but 1 hypospadias repair preserved the integrity of the urethral plate. Statistical significance was considered at  $p < 0.05$ .

**Results:** We were able to randomize between the dressed and nondressed groups based on fresh versus redo cases, position of the urethral meatus, severity of chordee, use of epinephrine, duration of surgery, type of repair and chordee correction ( $p > 0.05$ ). Of 49 patients 44 (90%) had successful results in the dressed and nondressed groups. Postoperative calls were more common in the undressed group ( $p = 0.02$ ) but no particular complication was more common in either group ( $p > 0.05$ ). Mean followup was 1 year, and there was no clinical or statistical difference between the dressed and nondressed groups with regard to success of the operation ( $p > 0.05$ ).

**Conclusions:** The success rate for hypospadias surgery that preserves the urethral plate is independent of dressing usage. Dressings may not be indicated for all hypospadias repairs.

KEY WORDS: hypospadias, bandages, penis

There are a great number of hypospadias repairs and types of hypospadias dressings.<sup>1-11</sup> As repairs become more complicated dressings often become more complicated as well. Perhaps the most complicated dressing is the pantaloon spica cast, which is an effective method for postoperative immobilization after free graft hypospadias repair, and avoids a weeklong hospitalization with immobilization of the patient.<sup>12</sup> In a large survey of pediatric urologists in 1981, 95% of the surgeons believed that dressings had a bearing on the outcome of hypospadias repair. The most significant postoperative measure for success was "the overwhelming recommendation of complete bedrest for an average of 5 days."<sup>1</sup>

Potential advantages of dressings after hypospadias repair include immobilization of the repair, improving tissue adherence, protecting suture lines, and preventing edema and bleeding. Potential disadvantages of dressings include production of ischemia, infection, inability to inspect the wound, difficulty in keeping clean and pain during dressing removal. Currently there is no consensus as to the optimum dressing among pediatric urologists, which explains the wide variety of dressings available. We compared the success and complications of hypospadias repair with and without dressings in a prospective randomized manner.

### METHODS

**Demographics.** A total of 100 consecutive children with hypospadias who presented between July 1997 and August 1999 were prospectively randomized to receive or not receive a postoperative dressing. Study inclusion criterion was any child 0 to 18 years old with hypospadias. Mean patient age was 22 months (median 9, range 2 to 180). Known coagulopa-

thy was a preoperative exclusion criterion, which did not occur in any case, and oozing at the end of the procedure was an intraoperative exclusion criterion, which occurred in 1 case each from the dressed and nondressed groups. After these 2 patients were excluded from study there were 98 patients for analysis, including 49 in the dressed and 49 in the nondressed group. Hypospadias repair was primary in 88 cases and secondary in 10. The position of the urethral meatus was glanular or subcoronal in 48 patients, distal, mid or proximal penile shaft in 32 and penoscrotal, scrotal or perineal in 8. Ten patients had the megameatus intact prepuce variant of hypospadias. Mild, moderate and severe ventral penile chordee was present in 30, 17 and 3 patients, respectively.

**Dressing and repairs.** Patients in the dressed group received a transparent, gas permeable, waterproof, hypoallergenic, nonlatex sterile film. The dressing was cut to the length of the penis as measured between the penopubic junction and supracoronal glans, and 2 dressings were wrapped around the shaft of the penis in opposing directions. Parents removed dressings at home on postoperative day 2 or sooner if they became soiled. Any difficulty in removing the dressing was managed by soaking the dressing off in a tub of warm water. When no dressing was applied only bacitracin ointment was placed on the glans.

An 8 or 10Fr silicone tube was used as a penile urethral stent in all primary repairs except for 1 case of perineoscrotal hypospadias. This patient had continuous drainage with an 8Fr silicone tube and a double diaper was used. Penile urethral silicone stents were left in place for 1 week for distal hypospadias repairs, 2 weeks for proximal hypospadias re-

pair and 3 weeks for penoscrotal or more severe hypospadias cases. All except 1 patient underwent procedures that preserved the integrity of the urethral plate (table 1).<sup>13</sup> Durham-Smith de-epithelialized skin flaps were interposed between the skin and urethroplasty for nonglanular hypospadias repairs.<sup>14</sup>

*Parameters evaluated.* For each patient position of the urethral meatus, degree of chordee, use of epinephrine or tourniquet, use of a postoperative catheter, length of surgery (minutes), type of repair and type of orthoplasty were recorded intraoperatively. Postoperatively the number of calls with the concern noted, hematoma or bleeding, position of urethral meatus, persistence or absence of chordee, good skin cosmesis, need for secondary procedures and whether the dressing made a difference or not were recorded. Success was defined as a glanular meatus, single forward directed stream, unimpeded voiding, absence of penile ventral chordee, good skin cosmesis and no need for any secondary procedure.

*Statistics.* Randomization was accomplished with a random number generator from a computer software program. Approval was obtained from the Institutional Review Board at the University of Louisville School of Medicine, and informed written consent was obtained from all parents. A power analysis was performed before the study to estimate the sample size required per group when using the Z statistic to compare proportions of dichotomous variables. Using a power of 80% and 2-tailed  $\alpha = 0.05$  a minimum of 43 patients in each group would be needed to detect a significant difference with  $p_1 = 0.1$  and expected difference between  $p_1$  and  $p_2 = 0.25$ . To assure randomization between the 2 groups and analyze differences postoperatively the Student 2-tailed t test, Fisher exact test and chi-square test for contingency tables  $2 \times 3$  or larger were used.

RESULTS

Between the dressed and nondressed groups randomization of all preoperative and intraoperative parameters was successful ( $p > 0.05$ , table 2). In the dressed group 30 patients and in the nondressed group 37 had penile urethral silicone stents ( $p = 0.09$ ). Orthoplasty was required in 25 of the dressed and 25 of the nondressed cases ( $p = 0.50$ ). Mean time for surgery in the 98 cases was 68 minutes (range 20 to 210, median 60). Mean time for surgery was 70 and 68 minutes ( $p = 0.73$ ), respectively, in the dressed and nondressed groups.

*Success and complications.* Hypospadias repairs were successful in 44 (90%) patients in both groups. Success was defined as a glanular meatus, single forward directed stream, unimpeded voiding, absence of penile chordee, good skin cosmesis and no need for any secondary procedure. There was no observed clinical or statistical difference between the dressed and nondressed groups in terms of postoperative outcome ( $p > 0.05$ ). Only adolescents and children with scrotal or perineoscrotal repairs were hospitalized postoperatively. Mild bleeding or a small hematoma, which usually developed in the re-

TABLE 1. Hypospadias repairs preserved the urethral plate

	No. Dressed	No. Nondressed
MAGPI	14	12
GAP/pyramid	7	5
Tubularized incised plate urethroplasty	27	30
Transverse ventral island flap onlay urethroplasty	1	2
Totals	49	49

TABLE 2. Randomization between dressed and nondressed hypospadias repairs

	No. Dressed	No. Nondressed
Primary cases	46	42
Glanular meatus	17	15
Distal meatus	16	22
Proximal meatus	10	8
Megameatus intact	6	4
prepuce variant of hypospadias		
Chordee:		
None	24	24
Mild	14	15
Moderate or severe	11	10
Epinephrine	31	37

For these parameters  $p > 0.05$ .

covery room, occurred in 2 of 49 patients in the dressed group and 5 of 49 in the nondressed group ( $p = 0.22$ ). Bleeding stopped spontaneously in all cases the day of surgery. There were no cases of meatal stenosis or urethral stricture (table 3). A patient with male pseudohermaphroditism, micropenis and severe chordee who underwent a single stage repair had mild chordee postoperatively. Redundant Byar's flaps were trimmed for better cosmesis in 1 patient with scrotal hypospadias and severe chordee, and 1 patient underwent separate removal of a proximally migrated urethral stent via cystoscopy.

*Followup.* It was not felt that a dressing or lack thereof produced morbidity of a significant nature in any patient. The parents were willing and able to remove the dressings at home and all patients except 1 did remove the dressings at home, which saved them an additional office visit. The only significant difference ( $p = 0.02$ ) noted in this study between the dressed and nondressed hypospadias repairs was the number of postoperative telephone calls (0.3 and 0.8 calls per patient in the dressed and nondressed group, respectively, median 0 range 0 to 6). Mean followup was 1 year. All preoperative, intraoperative and postoperative evaluations of the patients as well as surgical repairs were done by a single pediatric urologist (J. V. S.). There were 6 patients whose followup was limited to an initial postoperative visit.

DISCUSSION

We have demonstrated in a prospective randomized manner that there is no marked difference in the success rate for hypospadias surgery performed with or without a dressing. All of our preoperative and intraoperative parameters were successfully randomized between the dressed and nondressed groups. None of the outcome parameters except for the number of postoperative telephone calls was statistically or clinically significant between the dressed and nondressed hypospadias repairs. This finding is significant because there is no consensus among pediatric urologists regarding the best type of hypospadias dressing. It is possible that the type or presence of a dressing makes such a small difference that there is no effect on the success of certain hypospadias repairs. These dressings range anywhere from the simple,

TABLE 3. Complication rate similar with or without dressing following hypospadias repair

	No. Dressed	No. Nondressed
Meatal regression	0	2
Fistula	4	1
Stenosis	0	0
Chordee	1	0
Cosmesis	0	1
Stent migration	0	1
Totals	5	5

All  $p > 0.05$ .

transparent, bio-occlusive membranes to the pantaloons spica cast, which requires a saw for removal.

We believe that part of the reason that surgical dressings had such a minimal role in our success rate was the type of hypospadias repair performed. Tubularized incised plate urethroplasty was our preferred procedure in most cases.<sup>13</sup> This operation preserves the entire urethral plate and relies on lateral mobilization and tubularization of the urethral plate after a relaxing incision to the dorsal part of the urethral plate. The urethral plate is left attached to the corpora and it is unlikely that any hematoma, edema or bleeding could disrupt this particular type of repair. This outcome may not be true for creation of a new tube with either a graft or a flap after division of the urethral plate. Bleeding or edema could interpose into the potential space between the corpora and tube urethroplasty, and push the tube away from the corpora, thereby disrupting the repair or hindering healing. In all but 1 case we preserved the urethral plate, and our results may not be generalized to those procedures that disrupt the urethral plate.

A reason for applying a dressing is to conceal all or part of the penis from parental view. However, it is important that the surgeon and parents are able to see the penis. The only parameter we noted that was different between the dressed and nondressed hypospadias repairs was the number of telephone calls from parents. Because a dressing prevents edema and provides partial obscuration, the penis may look better during parental inspection. Since a dressing that is left on for a short postoperative period is unlikely to cause a problem, it would still be reasonable to use a dressing for 2 days or less. The transparent films we used are economical, waterproof, gas permeable, nonlatex, hypoallergenic and sterile. There are now more than a dozen of such films available and the characteristics continue to improve. These dressings are formfitting to the penis and cut appropriately to cover the penile shaft and part of the glans. Since we believe that dressings have most of their beneficial effects 1 or 2 days after surgery, we had parents remove them after that period at home, which was well tolerated by the majority. We believe that leaving dressings in place for a longer period creates difficulty in keeping the repair clean and may contribute to ischemia in certain cases.

Since completion of this study we have modified our surgical practice to include dressings on any repair that has persistent oozing during or at the end of the procedure. Tube urethroplasty and repairs that disrupt the bond of the urethral plate to the underlying corpora may also benefit from a dressing. Procedures that augment the urethral plate, such as the onlay urethroplasty, were performed in a limited num-

ber of patients in our series, and a firm recommendation regarding these patients is not possible. Graft urethroplasty was not performed in our series, and these patients stand to gain the most from a dressing left in place for 5 to 7 days. It is unlikely that bed rest and immobilization of flap urethroplasty are indicated as suggested 20 years ago.<sup>1</sup>

#### CONCLUSIONS

There was no marked clinical or statistical difference in the success rate for hypospadias repairs using the urethral plate to create a neourethra performed with or without a dressing. Use of dressings for hypospadias repair that preserve the urethral plate may not be indicated. These findings may not apply to hypospadias repairs that produce a potential space between the urethral plate and the corpora, and to graft urethroplasty.

#### REFERENCES

1. Cromie, W. J. and Bellinger, M. F.: Hypospadias dressings and diversions. *Urol Clin North Am*, **8**: 545, 1981
2. Redman, J. F. and Smith, J. P.: Surgical dressing for hypospadias repair. *Urology*, **4**: 739, 1974
3. Okafo, B. A. and Kiruluta, H. G.: Penile dressing after hypospadias surgery. *Can J Surg*, **28**: 387, 1985
4. Whitaker, R. H. and Dennis, M. J. S.: Silastic foam dressing in hypospadias surgery. *Ann R Coll Surg Engl*, **69**: 59, 1987
5. Vordermark, J. S., II: Adhesive membrane: a new dressing for hypospadias. *Urology*, suppl., **29**: 33, 1987
6. Patil, U. B. and Alvarez, J.: Simple effective hypospadias repair dressing. *Urology*, **34**: 49, 1989
7. Gaylis, F. D., Sugar, E. C., Zaontz, M. R. et al: Silicone foam dressing for penis after reconstructive pediatric surgery. *Urology*, **33**: 296, 1989
8. Cabral, B. H. P. and Gonzalez, R.: Use of urethral drainage tube and dressings in hypospadias repair. *Urology*, **33**: 327, 1989
9. Tan, K. K. and Reid, C. D.: Ideas and innovations: a simple penile dressing following hypospadias surgery. *Br J Plast Surg*, **43**: 628, 1990
10. Ohsumi, N.: Postoperative compressive penile dressing using fibrin seal (Tisseel) and tulle gauze for hypospadias repair. *Plast Reconstr Surg*, **101**: 1737, 1998
11. Redman, J. F.: A dressing technique that facilitates outpatient hypospadias surgery. *Urology*, **37**: 248, 1991
12. Cilento, B. G., Stock, J. A. and Kaplan, G. W.: Pantaloons spica cast: an effective method for postoperative immobilization after free graft hypospadias repair. *J Urol*, **157**: 1882, 1997
13. Snodgrass, W.: Tubularized incised plate urethroplasty for distal hypospadias. *J Urol*, **151**: 464, 1994
14. Smith, D.: A de-epithelialised overlap flap technique in the repair of hypospadias. *Br J Plast Surg*, **26**: 106, 1973

#### DISCUSSION

*Dr. Umesh Patil.* About 70% of hypospadias repairs are distal and you do not need to apply a dressing. Do you make a distinction in which of your cases you put on a dressing?

*Dr. John Van Savage.* We studied 100 consecutive patients with proximal and distal hypospadias, and there was no difference either statistically or clinically with the success of the operation with or without a dressing.

*Doctor Patil.* So do you recommend that future surgeons stop the dressing on these patients?

*Doctor Van Savage.* Yes. The only time I will put on a dressing is for extensive lysis of chordee when I expect a lot of swelling or if there is oozing at the end of the procedure and then I will use a dressing for 1 or 2 days. Otherwise I do not use any dressing.