

UROGENITAL TRAUMA

Improvement of hemostasis in open and laparoscopically performed partial nephrectomy using a gelatin matrix-thrombin tissue sealant (FloSeal)

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Objectives: Long-term follow-up studies have demonstrated that effective local tumor control and long-term tumor-free progression rates can be achieved by nephron-sparing surgery. However, hemostasis is a major issue, and the lack of effective means of hemostasis has limited the wider use of the laparoscopic approach to nephron-sparing surgery.

Methods: Between January 2001 and April 2002, 25 patients with renal cell carcinoma were treated with partial nephrectomy using a two-component tissue sealant (FloSeal). The median age was 54 years (range 42 to 71). The follow-up time was 1 to 12 months (median 3.5). The tumor diameter ranged from 2 to 5 cm (median 2.8). Fifteen cases were performed by open retroperitoneal surgery, and 10 cases were performed laparoscopically. The two-component tissue sealant (consisting of a gelatin matrix granula component and a thrombin component) was applied after resection of the tumor and before perfusion of the kidney. The following parameters were recorded: time until complete hemostasis was achieved; decrease in postoperative hemoglobin level; postoperative bleeding; and presence or absence of a perirenal hematoma 24 hours and 10 days postoperatively by ultrasonography.

Results: After application of the tissue sealant for 1 to 2 minutes to the moist resection site, hemostasis was immediate in all cases. During the laparoscopically performed partial nephrectomies, a laparoscopic applicator was used to avoid wasting the tissue sealant within the dead space of the instrument. When reperfusion of the kidney was established, hemostasis was maintained. The decrease in postoperative hemoglobin level ranged from 0.3 to 1.2 points (median 0.7). None of the patients required blood transfusions. No postoperative bleeding occurred. The ultrasound examination 24 hours and 10 days postoperatively demonstrated the absence of a significant perirenal hematoma.

Conclusions: The two-component tissue sealant FloSeal provided immediate and durable hemostasis in open and laparoscopically performed partial nephrectomies. The tissue sealant may provide a tool to expand the possibilities of laparoscopic nephron-sparing surgery.

Editorial Comment

Major bleeding is an issue for both renal trauma surgery and partial nephrectomy. In this study, the authors validate the use of a novel thrombin hemostatic agent that works much better than any similar material from the past, for use against bleeding seen in laparoscopic partial nephrectomy. Although not specifically a trauma study, I believe that the hemostasis seen in this study could also be welcome in renal trauma surgery (renorrhaphy). In the past, few hemostatic agents had been truly helpful in stemming hemorrhage from the bleeding kidney, and intraoperative and postoperative blood loss remained a problem. Worse, during some renal trauma surgery, potentially salvageable kidneys were removed iatrogenically because of brisk bleeding. Now, the invention of highly concentrated thrombin in a gelatin matrix (FloSeal; Baxter) allows the stemming of even spurting blood, and forms a clot, which is both strong and lasting. This will surely decrease the nephrectomy rate during attempted renorrhaphy.

Company literature shows Floseal stopping bleeding from experimentally lacerated porcine heart and inferior vena cava. The clot that is formed is not pushed out by the pressure of blood, even in the heart. I have

personally validated these findings in pigs, where FloSeal stopped bleeding from stab wounds to the liver, spleen and kidney almost instantaneously, and stopped bleeding from lacerated IVC after 3 minutes of light pressure with a moist sponge. In humans, I have used FloSeal in open partial nephrectomy with identically excellent results to this paper. No renal vessels needed ligation, and no persistent or late bleeding was seen. A second application of FloSeal is sometimes needed if the first application does not stop all the bleeding. Warm ischemia time is decreased to minutes, even in large partial nephrectomy cases.

In this study, FloSeal was used in 25 partial nephrectomy patients as the sole means of bleeding control. 15 had open operations and 10 had laparoscopic surgery. Average time to complete hemostasis was less than 2 minutes, and no patients had postoperative bleeding. Finally, it appears that a very effective hemostatic agent is available for our everyday use.

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Effect of an institutional policy of nonoperative treatment of grades I to IV renal injuries

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Purpose: Nonoperative treatment of serious renal injuries has been advocated and yet to our knowledge the optimum level of operative treatment has not been established to date. We report a unique data set, in which patients with severe renal injuries were treated with an ultraconservative nonoperative approach during a period when urological consultation was not available at a major urban trauma center.

Materials and Methods: We retrospectively reviewed the charts of 51 patients identified with renal trauma in the Detroit Receiving Hospital trauma database from 1997 to 2001.

Results: Injuries were grades I to V in 15, 7, 11, 14 and 4 cases, respectively, and had a tendency toward serious injury. Renorrhaphy was never performed. Nephrectomy was done sparingly, only for grade V renal injuries and only in patients who were exsanguinating from the kidney. Two of the 4 patients with grade V injury died of multiple injuries, including massive head injuries. Only 2 of the patients treated nonoperatively (4%) had complications, including fever and hematuria in 1 each.

Conclusions: This data set seems to support an ultraconservative approach of limiting renal surgery to only patients with active exsanguination. The nephrectomy rate for 14 grade IV injuries, including some gunshot wounds to the kidney, was 0%. When comparing this rate with that in the literature, we would expect it to be 1 patient to as high as 10. This approach was safe and resulted in a low complication rate of 4%. Series in which more aggressive therapy for renal injuries is advocated should compare favorably to ultraconservative therapy if aggressive therapy is to continue to be widely advocated.

Editorial Comment

Most renal trauma literature is written by urologists, but at many centers the General Surgery trauma team not the urologist dictates what therapies are provided to injured patients. In some cases the trauma surgeons may elect not to consult the urology service, or they may elect to remove a briskly bleeding kidney even before urology can be notified. At our trauma center, the trauma surgeons, many of them internationally famous

names, correctly (I believe) determined that most severely injured kidneys healed without the need for surgery. Even 6 patients with gunshot wound were given a trial of conservative therapy - all of them successfully. Only those who were actively bleeding to death (in the estimation of the attending general surgeon) had renal surgery, and that was a speedy nephrectomy in all cases. In this way, these surgeons have turned classic urologic trauma teaching on its head, reducing the operative rate over that reported in previous urologic series, and most importantly decreasing the rate of nephrectomy towards 0% for Grade I-IV injuries. This series mirrors the general trend towards conservative therapy in trauma, and reports like it must be closely followed by anyone with an interest in treating renal injury. Less is turning out to be more in the field of renal trauma. While it takes more courage to observe the patient than go to the operating room, it may ultimately turn out to be the best treatment in the majority of patients.

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PATHOLOGY

Multiple measures of carcinoma extent versus perineural invasion in prostate needle biopsy tissue in prediction of pathologic stage in a screening population

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The capacity of perineural invasion by carcinoma in prostate needle biopsy tissue to independently predict pathologic stage in radical prostatectomy tissues remains uncertain. We sought to determine, in a prostate specific antigen-based screening population, the ability of needle biopsy histologic grade, tumor extent, and perineural invasion to independently predict pathologic stage and margin status in the whole prostate gland. Perineural invasion, Gleason grade, percentage Gleason pattern 4/5 carcinoma, and multiple measures of needle biopsy tumor extent, including number of positive cores, percentage of positive cores, total percentage of carcinoma, greatest percentage of carcinoma in a single core, and total carcinoma length in millimeters, were captured for 215 men from a prostate specific antigen-based screening program diagnosed with prostate cancer in a median of six procured needle biopsy cores. Pathologic stage and surgical margin status were evaluated in corresponding completely embedded radical prostatectomy specimens. A logistic regression model was used to relate the endpoints of extraprostatic extension by carcinoma and/or positive margins to needle biopsy tissue findings. In univariate analyses, total percentage of carcinoma ($p = 0.003$), greatest percentage of carcinoma in a single core ($p = 0.004$), total tumor length in millimeters ($p = 0.009$), and fraction of positive cores ($p = 0.02$) were all significantly associated with extraprostatic (pT3) carcinoma, whereas all five measures of carcinoma extent in needle biopsy tissue were related to positive margins. Correlation coefficient determinations showed that all five measures of needle biopsy carcinoma extent were highly interrelated. In multivariate analyses, total percentage of carcinoma was significantly related to pathologic T stage ($p = 0.003$) and positive margins ($p = 0.0002$). In a multivariate model with the radical prostatectomy whole gland endpoint of either pT3 disease or positive margins, fraction of positive cores ($p = 0.00001$) was the only variable with significant predictive value. Perineural invasion by carcinoma in needle biopsy tissue was detected in 11% of cases. Neither presence