A MULTIVARIATE ANALYSIS OF RISK FACTORS ASSOCIATED WITH SUBCAPSULAR HEMATOMA FORMATION FOLLOWING ELECTROMAGNETIC SHOCK WAVE LITHOTRIPSY

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ABSTRACT

Purpose: Subcapsular or perinephric hematoma is one of the most frequent and potentially serious complications of extracorporeal shock wave lithotripsy (SWL). We determined the incidence of and risk factors for renal hematomas following electromagnetic shock wave lithotripsy.

Materials and Methods: Between February 1999 and August 2003, 570 SWL treatments were performed using a Modulith SLX electromagnetic lithotriptor (Storz, St. Louis, Missouri). A total of 415 of these treatments in 317 patients were performed for stones in the renal pelvis or calices and these treatment episodes represent the study group reported. Treatment episodes were reviewed from a prospective institutional review board approved registry and analyzed for patient age, gender, body mass index, mean arterial pressure at induction, stone location, total number of shock waves and peak shock wave intensity.

Results: Following these 415 episodes subcapsular or perinephric hematomas developed in 17 patients for an overall incidence of 4.1%. The probability of hematoma after shock wave lithotripsy increased significantly as patient age at treatment increased, such that the probability of hematoma was estimated to be 1.67 times greater for each 10-year incremental increase in patient age. None of the other variables analyzed were significantly related to the incidence of hematoma formation at the 0.05 level.

Conclusions: The incidence of renal hematoma formation following electromagnetic SWL for renal calculi was 4.1%. The probability of hematoma increased significantly with increasing patient age but it was not associated with increasing mean arterial pressure at treatment. These findings are in contrast to previous reports of hematoma associated with electrohydraulic SWL. These differences may be a consequence of the smaller focal zone and higher peak pressure associated with Storz Modulith electromagnetic SWL and, just as importantly, a consequence of the difference in the manner in which blood pressure was defined.

KEY WORDS: kidney, kidney calculi, hematoma, lithotripsy

Extracorporeal shock wave lithotripsy (SWL) is an effective, minimally invasive treatment option in patients with upper urinary tract calculi. The reported rate of complications associated with SWL varies, primarily as a function of different definitions of complications and types of imaging performed after SWL. However, virtually all studies of the bio-effects and complications of SWL include the development of subcapsular and perirenal hematomas.1–3 The incidence of and risk factors for hematoma formation have been described in patients treated with electrohydraulic lithotripsy. Potential factors that have been examined are bleeding diathesis, the use of drugs with antplatelet activity, hypertension, obesity, diabetes mellitus, and the number and intensity of shock waves. In the setting of electrohydraulic lithotripsy none of these factors have been consistently proved to be a risk, although hypertension remain a plausible factor.3–5 In contrast, reports of hematoma associated with electromagnetic lithotripsy are few. Therefore, we determined the incidence of and risks for hematoma formation associated with electromagnetic SWL.

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PATIENTS AND METHODS

Between February 1999 and August 2003, 570 consecutive extracorporeal SWL procedures were performed using a Storz Modulith SLX electromagnetic lithotriptor. Of these episodes a total of 415 were performed for renal pelvic or caliceal stones in 317 unique patients. These renal stone treatment episodes and patients form the study group reported.

All treatments were performed on an outpatient basis using general anesthesia with a laryngeal mask or endotracheal airway. Pretreatment evaluation in all patients consisted of a complete history with attention to potential bleeding disorders and physical examination. Chest x-ray and electrocardiogram were obtained when indicated because of history or patient age. Patients underwent a complete blood and platelet count, basic metabolic panel (electrolytes, serum creatinine and blood urea nitrogen) or extended metabolic panel that included liver enzymes, urinalysis and culture, and, when history suggested, prothrombin time and partial thromboplastin time.

All patients were specifically instructed to withhold any anticoagulative medications for 9 to 14 days prior to intervention. Such medications included but were not limited to aspirin containing products, nonsteroidal anti-inflammatory drugs and any other inhibitors of platelet function. Patients on warfarin were evaluated specifically for a need for hepa-
In most patients warfarin was stopped at least 4 days preoperatively and a normal prothrombin time was determined prior to treatment. In a few instances warfarin was discontinued and heparin was started intravenously and stopped at least 8 hours prior to treatment with a normal partial thromboplastin time required for treatment. Routine postoperative evaluation included a plain x-ray of the kidneys, ureters and bladder, and ultrasound approximately 4 weeks after treatment. When symptoms suggested the need for earlier evaluation, noncontrast flank pain protocol computerized tomography or ultrasound was performed earlier.

Study data were obtained from an institutional review board approved, prospective shock wave lithotripsy registry. Potential risk factors evaluated were patient gender, age, body mass index (BMI), mean arterial pressure (MAP) at induction, stone location, total number of shock waves and peak shock wave intensity. Multivariate analysis of these potential risk factors was then performed to determine which factors might be associated with post-SWL perirenal or subcapsular hematomas.

Statistical methods. The median, and 25th (Q1) and 75th (Q3) percentile are reported for continuous variables and frequency, and percent is reported for categorical variables. Logistic regression using generalized estimating equations (GEEs) with the compound symmetry correlation structure was used to model the occurrence of hematoma. This allowed adjustment for possible correlation among episodes in the same patient as well as adjustment among and within episodes in the same patients for variables pertaining to kidney stone and shock wave data. ORs for an association with hematoma with the 95% CI are reported. Tests were 2-tailed with a significance level of 0.05. Analyses were done with SAS 8.2 (SAS Institute, Cary, North Carolina).

RESULTS

Table 1 lists patient demographics and stone characteristics in the study group, which included 323 women and 185 men 10.8 to 87.6 years old (median age 51.9). Of treated stones 357 (79%) were caliceal in location, while 96 (21%) were in the renal pelvis. These 317 patients underwent a total of 415 treatment sessions (average 1.3 per patient). All repeat treatments were delayed at least 4 weeks from the initial episode. Of the 415 treatment episodes 17 (4.1%) resulted in subcapsular or perirenal hematomas, of which 3 (17.6%) were symptomatic. Thus, in this study the overall rate of symptomatic hematoma formation was 0.7%. Ten patients underwent bilateral simultaneous treatment. None of those episodes resulted in hematoma formation.

Table 2 shows an analysis of continuous variables and their association with post-SWL hematoma formation. When comparing patients who did and did not have hematoma after treatment, there was no statistical difference in the body mass index, total number of shock waves or peak shock wave intensity. Likewise, there was no significant difference in MAP between patients who had a hematoma compared to those who did not (mean MAP 93.3 vs 90.0 mm Hg, respectively). However, the probability of hematoma increased significantly as patient age at treatment increased (p = 0.009). For every 10-year increase in treatment age the probability of hematoma increased 1.67 times.

Table 3 shows a comparison of post-SWL hematomas by categorical variables. Neither male vs female sex nor left vs right side had any significant impact on the probability of hematoma formation. Treated stones were caliceal in location in 357 episodes (79%) compared to a renal pelvic location in 96 (21%). The total number of stone locations exceeded the total number of treatments because some patients had stones at more than 1 location. Hematomas developed in 15 of the 357 treated caliceal stones (4.2%). In contrast, hematomas developed in 2 of 96 treated renal pelvic stones (2.1%). However, the fact that this apparent difference did not achieve statistical significance (p = 0.34) may have been a consequence of the relatively few patients treated for renal pelvic stones compared to the number treated for caliceal stones. As such, this lack of significance may be a function of the power of the study rather than a reflection of a true physiological consequence.

DISCUSSION

A frequently observed direct adverse effect of SWL is the development of perirenal or subcapsular hematomas. Several investigators have reported the incidence and risk factors for hematomas induced by the HM-3 electrohydraulic lithotriptor (Dornier Medical Systems, Marietta, Georgia). Chaussy et al reported an incidence of hematoma of 0.6% and other investigators likewise found a low incidence of 0.2% to 1.5%. In those reports patients were generally assessed by renal ultrasonography only after a clinical episode and our 0.7% incidence of symptomatic hematoma formation is entirely consistent with those reports. However, when computerized tomography or magnetic resonance imaging is performed routinely after SWL, the hematoma rate increases to as high as 20% to 25%. Therefore, this discrepancy in reported rates of post-SWL hematoma is mainly due to the greater sensitivity of computerized tomography and magnetic resonance imaging for detecting small hematomas and the fact that not all affected patients become symptomatic. Therefore, many affected asymptomatic patients may have escaped diagnostic imaging in those previous studies. Thus, in our study the overall 4.1% incidence of hematoma formation, which lies between those previously reported extremes, is readily explained by our routine use of post-SWL ultrasound imaging in all patients, not just symptomatic ones, while accepting that ultrasound is less sensitive than computerized tomography or magnetic resonance imaging.

In addition to patient characteristics, mechanical factors (catheter and focus size, shock wave shape, power and frequency, and method of shock wave generation) may be important variables in renal hematoma formation after SWL. The Storz Modulith lithotriptor is an electromagnetic generated lithotriptor and it differs from the Dornier HM-3 in the shock wave generating and focusing systems. In the Storz Modulith SLX unit used in this study shock waves are generated by a cylindrical electromagnetic coil and focused by a parabolic reflector. Shock waves are coupled to the patient by a water filled cushion. The unit is designed with an ellipsoid aperture of 30 cm and a focal distance of 16.5 cm. However, the size of the focal zone varies depending on the energy level used. At maximal energy the focal zone is 6 × 6 × 28 mm, while decreasing the energy results in a broadening and shortening of the focal zone marginally. In contrast, the Dornier electrohydraulic unit has an ellipsoid aperture of 17 cm, a focal distance of 13 cm and a focal zone of 7.5 × 38 mm. Shock waves are generated by an electrohydraulic spark gap electrode and coupled using water that directly abuts the patient. Perhaps as a result of the smaller focal zone and higher peak energy, the Storz Modulith electromagnetic

| Table 1. Study group patient demographics and stone characteristics |
|------------------|------------------|------------------|------------------|
| No. treatments   | 415              |
| No. pts          | 317              |
| No. men/women    | 185/132          |
| Median age (yrs): (range) | 51.95 (10.8–87.6) |
| Total No. stones | 453              |
| Renal stone location: | |
| Pelvis           | 96               |
| Calices          | 357              |
| Rt               | 188              |
| Lt               | 265              |

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lithotriptor may have a higher incidence of hematoma forma-
tion than some previously studied electrohydraulic units.14
The etiology of hematoma formation after SWL remains
unclear. In our study we evaluated potential risk factors
regarding patient and stone characteristics, and the physical
parameters of SWL treatment. We found no correlation of
hematoma occurrence with gender, stone location, BMI,
mean arterial pressure at induction, total number of shock
waves or peak shock wave intensity. While a correlation of
hematoma formation to total number of shock waves applied
would seem intuitive, in this study most patients in fact were
treated with 3,000 shock waves per renal unit. As such, there
was not a wide range in the number of shock waves per
treatment to analyze. Likewise, most patients were treated
at a power level of 7 to 8, again with little variability between
treatment episodes.

In this study advancing patient age at treatment proved to
cause a significant risk for hematoma formation. The proba-
bility of hematoma significantly increased as treatment age
increased (p = 0.009). For every 10-year increase in treat-
ment age the probability of hematoma increased 1.67 times.
While this study was not designed to determine why this was
the case, an age related change in renal microvascular anat-
omy and compliance seems plausible. It is worth noting that
treatment for a caliceal calculus was 2 times more likely
to result in hematoma formation than treatment for a
renal pelvic calculus. While this finding was not statistically
significant, shock waves arriving at caliceal calculi travel
through more parenchyma than those reaching renal pelvic
calci and, therefore, perhaps they are more likely to induce
hematoma formation.

Knapp et al reported that patients with preexisting hyper-
tension, particularly those with poorly controlled hyperten-
sion, had a significantly increased incidence of hematoma
formation after hydraulic generated SWL.4 The over-
all incidence of hematoma was 2.5% but this increased to
3.8% in patients with unsatisfactory control of hypertension,
although the definition of poorly controlled hypertension as
temporally related to lithotripsy treatment is not clear in
that report. Coftcoat et al noted obesity in 2 of 3 patients
who had post-SWL hematomas, although their study did not
allow determination of any statistical significance with such a
small number of affected patients.3 Similarly Newman and
Saltzman reported on 9 patients with symptomatic hemato-
mas after SWL.5 In that retrospective review hypertension,
diabetes, coronary artery disease and obesity were identified
as common factors. However, again in that small study there
was no comparison to treated patients who did not have
hematomas. As such, no statistically relevant conclusions
could be made.

In this study we chose to look specifically at MAP at in-
duction as a potentially more objective way to evaluate the
role of blood pressure at treatment as a risk for post-SWL
hematoma formation. We compared MAP in patients who did
and did not have hematomas. In our study we found no
relationship between hematoma formation and elevated
MAP at induction. The difference in this finding compared to
previous studies may have been a result of the smaller focal
zone and higher local peak pressure of electromagnetic SWL
compared to hydraulic sources. However, a difference in
the timing, recording and definition of pretreatment blood
pressure as a potential risk seems at least as likely an ex-
planation.

**CONCLUSIONS**

The incidence of renal hematoma following electromagnetic
SWL is 4.1% when patients are routinely screened with ultrasound after treatment. The probability of hema-
toma increases significantly with increasing patient age at
treatment. Treatment for caliceal calculi was 2 times more
likely to result in hematoma formation than treatment for
renal pelvic calculi but this was not statistically signifi-
cant. In this study hematomas associated with electromagnetic
SWL were not associated with increased MAP at
treatment. These findings are in apparent contrast to pre-
vious reports of hematomas associated with hydraulic
SWL. This difference may have resulted from the
smaller focal zone and higher peak pressures associated
with electromagnetic SWL, although an additional or al-
terative explanation may be the definition of blood pres-
sure at treatment. Finally, the data regarding an increas-
ing incidence of hematoma formation with advancing
patient age seems compelling and worth further study. An
age related change in intrarenal small vessel anatomy and
compliance might ultimately prove important.
REFERENCES


