Anti-miss-shot control device for selective stone disintegration in extracorporeal shock wave lithotripsy

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Abstract. A new device to prevent erroneously focused shock waves to the renal parenchyma during extracorporeal shock wave lithotripsy (ESWL) has been developed; an anti-miss-shot control device (AMCD) and experiments have been conducted to evaluate its effectiveness. For shock wave generation and stone localization, piezoceramic elements (PSE) and ultrasound localization, respectively were used. After stone localization, probing ultrasounds (PU) were emitted from the PSE towards the focal region and the reflected sound levels (RSL) were monitored by the PSE which also functioned as a microphone. A direct hit by the PU to the stone or a miss was judged from the RSL, i.e. a high RSL indicates a direct hit and a low RSL indicates a miss. Shock waves were generated only when the RSL exceeded the level which indicated a direct hit. The experimental results showed that the injury to the renal parenchyma was decreased by using the AMCD. Clinical application of the AMCD is expected to increase the safety of ESWL.

Key words: ESWL, Shock wave, Anti-miss-shot device, Tissue injury

1. Introduction

It was found in previous experiments (Ioritani et al. 1989) that renal tissue injury occurred at focused shock wave pressures of 20 MPa which was much lower than the 60 MPa that was needed to disintegrate the calculi during ESWL. This indicates that the renal tissue is inevitably injured when shock waves are erroneously focused to it. This condition is likely to occur during ESWL treatment because the kidney which contains the stone, changes its location with breathing movement. High frequency jet ventilation, HFJV¹ (Schulte et al. 1985) has been reported to be effective in stabilizing the stone movement associated with breathing movement. However, this method is applicable only under general anesthesia and requires special equipment such as a ventilation control unit.

In order to selectively disintegrate the targeted stone and to protect the renal tissue from erroneous shock wave exposure, we have developed an anti-miss-shot control device AMCD and conducted experiments to evaluate its effectiveness.

2. Materials and method

Shock waves were generated by a shock wave applicator of an over-head water-bag type which was specially designed and constructed by the Toshiba Corporation, Japan. The piezoceramic wave generator was immersed in water and a focused wave was transmitted into the test body through a plastic membrane. The generator consisted of 24 piezoceramic elements which were arranged to form a sector of a spherical dish of 300 mm diameter. The maximum pressure at the focus in water was estimated to be 100 MPa when the generator was excited at 4 kV excitation pulse voltage. The one half maximum pressure region was 2x2x19 mm. Details of this apparatus are reported in Okazaki et al. (1989). A schematic diagram and a concept of the AMCD are shown in Fig. 1. The judgement as to whether the probing ultrasounds directly hit the stone or not is conducted by a comparator. Since the judging interval of the comparator is very short, about 200 ms, the shock waves are expected to hit the stone without delay.

For the experiments, 8 adult mongrel dogs of both sexes, weighing 10 kg each were divided into three groups; in the first group, 3 dogs were subjected to ESWL using the AMCD, in the second group, 3 dogs

¹ HFJV is an anesthesia technique to control and to minimize the movement of the brain during surgery. This technique was used mainly in the field of neurosurgery.
Fig. 1. Schematic diagram and concept of the AMCD. For shock wave generation and stone localization, PSE and ultrasound localization are used. First, ultrasound stone localization is performed by a sonoprobe (3.75 MHz) installed in the center of the dish. Then, probing ultrasounds (5 μs duration at 2 shots per second) are generated from the shock wave generator to the focal region, and the RSL from the region (2x2x19 mm) are detected by the generator acting as a microphone. A hit or miss is judged by a comparator from the RSL, i.e. a high level indicating a hit and a low level indicating miss. Shock waves are generated when the RSL is judged as being above the “hitting level”.

were treated by ESWL without using the AMCD and the final 2 dogs served as a control. All dogs were prepared as follows: the right ureter was ligated by a 3-0 silk thread at its lowest part. One week after the operation a human calculus of 6 mm diameter (mixed calcium oxalate and calcium phosphate) or a model calculus of 6 mm diameter (activated alumina) was transplanted into the dilated right renal pelvis.

The ligated part of the ureter was removed and an ureterocystostomy was performed using 4-0 polyalcoholic suture materials. All surgical procedures were performed under general anesthesia (Thiopental Sodium, i.v. 25 mg/kg body weight) with aseptic precautions. One month after the second operation the animals, except for the 2 control dogs, were used for the stone disintegration experiment under the same general anesthesia.

For the ESWL, 1,000 shots at a frequency of 2 Hz with an excitation voltage of 4 kV were targeted at the stone under the general anesthesia mentioned above. After each experiment the dog was sacrificed by an injection of potassium chloride, and the kidney was removed for macroscopic and microscopic examination. The bleeding lesion (bleeding area, length x width) in the kidney was measured on the cut surface of the removed kidney. The stone size was measured on section paper.

3. Results

Ultrasonograms taken during the ESWL are shown in Fig. 2. As shown in Fig. 2a, high RSL were obtained when the stone was located in the focal region. It was confirmed by direct inspection on the ultrasonic display screen that shock waves were generated only when high RSL were detected. Fig. 2b shows an ultrasonogram when the stone deviated from the focal region. In this situation the RSL remained low and shock waves were not generated.

In all experimental animals, the stone had been disintegrated in the renal pelvis. Macroscopic comparisons between the kidneys treated with and without the AMCD have disclosed that faint bleeding lesions existed in the kidneys treated by the AMCD, but in those treated without the AMCD, bleeding lesions were clearly observed in the renal parenchyma, Fig. 3. Microscopic examination revealed that intrarenal bleeding had developed in the kidneys treated by the AMCD as well as in those treated without the AMCD. However, the bleeding lesion area was small, and the severity of the bleeding was low in the former kidney compared to the latter. In addition to this, the stones were more completely disintegrated with the AMCD. These results are summarized in Table 1.

4. Discussion

Selective focusing of shock waves to the stone is necessary, not only to decrease the total number of exposures needed for stone disintegration but also to protect the renal parenchyma from the deleterious effects of the shock waves. It was found in previous experiments (Ioritani et al. 1989) that the pressure at the focal region for effective stone disintegration was above 60 MPa whereas the pressure inducing intrarenal bleeding was above 40 MPa (in the case of extravasation observed by an angiograph, > 20 MPa). These results indicate that there is no pressure-zone in which the renal tissue can be preserved in the intact condition if the stones are to be selectively destroyed. Therefore, to minimize renal tissue injury, precise stone localization with no erroneous shots to the renal parenchyma is essential. However, the precise targeting of the stone throughout extracorporeal

Table 1. Macroscopic bleeding lesion and stone fragmentation in dogs treated with and without the AMCD

<table>
<thead>
<tr>
<th>Dog Number</th>
<th>Bleeding Lesion (Kidney)</th>
<th>Stone Fragmentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>With the AMCD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. 1 (model stone)</td>
<td>+</td>
<td>x x</td>
</tr>
<tr>
<td>No. 2 (human stone)</td>
<td>-</td>
<td>x x</td>
</tr>
<tr>
<td>No. 3 (human stone)</td>
<td>+</td>
<td>x x</td>
</tr>
<tr>
<td>Without the AMCD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. 4 (model stone)</td>
<td>++</td>
<td>x</td>
</tr>
<tr>
<td>No. 5 (human stone)</td>
<td>++</td>
<td>x</td>
</tr>
<tr>
<td>No. 6 (human stone)</td>
<td>++</td>
<td>X X</td>
</tr>
</tbody>
</table>

+ Bleeding lesion <5 mm in width
++ Bleeding lesion >5 mm in width
- Bleeding lesion not observed
X Pulverized stone <3 mm
XX Pulverized stone <1 mm