Efficacy of Disposable Needles Versus Angiocath Needles for Therapeutic Abdominal Paracentesis

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Background: Disposable needle and angiocath needle are the two most commonly used needles for therapeutic abdominal paracentesis. The present study aims to compare the efficacy and complication rate between disposable needles and angiocath needles for therapeutic abdominal paracentesis.

Material and Method: The present study was an open-labelled study of patients indicated for therapeutic abdominal paracentesis at Siriraj Hospital during June to December 2009. Patients were assigned by physicians to either the disposable needle group (disposable needle No.18 used) or the angiocath group (angiocath needle No.16 used). Efficacy and complications were compared.

Results: A total of 100 patients were assigned to the disposable group, and 100 patients to the angiocath group. The disposable needle group had higher success rate by single attempt (97% vs. 84%, p = 0.006) and less failure (0 vs. 6%, p = 0.013). However, the ascites flow rate in the angiocath group was significantly greater (mean 67.1 vs. 53.1 ml/min, p = 0.012). Complications were fewer in the disposable needle group, particularly of abdominal wall hematoma (1% vs. 8%, p = 0.035). Traumatic tapping also occurred less often in the disposable needle group but was not statistically significant (3% vs. 9%, p = 0.134).

Conclusion: Compared with angiocath needles, disposable needles used for therapeutic abdominal paracentesis demonstrated higher success rate, fewer complications but slightly slower flow rate.

Keywords: Abdominal paracentesis, Angiocath, Disposable, Needle, Therapeutic, Efficacy

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Ascites is a common and clinically important condition in general practice. Abdominal paracentesis is a necessary procedure for both diagnostic and therapeutic purposes. Therapeutic abdominal paracentesis is now accepted as a treatment of symptomatic ascites in patients with cirrhosis^(1,2) or malignancy⁽³⁾. In the Western, many kinds of paracentesis needles have been used for therapeutic paracentesis including Caldwell spring needle⁽⁴⁾, multihole plastic needle with metal stylet^(1,2,5) and the less often recommended, angiocath needle⁽⁵⁾. In Thailand, due to the high costs and unavailability of Caldwell and multi-hole needles as well as the well-known safety of metal needles for diagnostic abdominal paracentesis⁽⁶⁾, metal needles are therefore used by

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many physicians for therapeutic abdominal paracentesis. Thus, disposable metal needle and angiocath needle are currently the two most commonly used needles for therapeutic abdominal paracentesis in Thailand. However, there has been no study comparing the efficacy and complication rates between these two needles. Many physicians prefer angiocath needles due to the availability of the larger-sized needles (i.e. No. 16) and the belief that they cause fewer traumatic complications than with disposable needle despite the fact that previous study has shown that complications of the metal needles are very rare⁽⁶⁾. However, angiocath needles are more expensive than disposable needles and we often observe kinking of the floppy needles and the needs of re-positioning of the angiocath needles during the procedure. By contrast, disposable needles may overcome all these problems and the authors rarely observe serious complications from the disposable needles. Therefore, if it is demonstrated that that disposable needles are superior to angiocath needles in terms of efficacy and

no difference in complication rates, using the disposable needles would be a safe and cost-saving alternative.

Thus, the authors conducted the present study to compare the efficacy and complication rates between disposable needles and angiocath needles for therapeutic abdominal paracentesis.

Material and Method

Patients

The present study is an open-labeled study. Patients over the age of 15 years who had moderate to marked symptomatic ascites and indicated for therapeutic abdominal paracentesis in the Department of Medicine, Siriraj Hospital during June to December 2009 were enrolled. Complete blood count and coagulogram were not routinely checked but were done when there were clinical clues of significant bleeding disorders. In that case, platelet count was corrected to the level above 50,000/mm³ and prothrombin time was corrected to the level of international normalized ratio (INR) of less than 1.5. An exclusion criterion was the patient with uncorrectable bleeding disorders.

Intervention

Patients were assigned to the disposable group (using disposable needle No.18) and the angiocath group (using angiocath needle No.16) by physicians who performed therapeutic abdominal paracentesis.

Therapeutic abdominal paracentesis was performed by 1) identifying the landmark for puncture by physical examination or ultrasonography, 2) painting that area with antiseptic agent adhering to the aseptic technique, 3) injecting the site with 1% lidocaine with adrenaline 5-10 ml, 4) inserting either a disposable needle or angiocath needle, 5) dressing the puncture site with two pieces of gauze measuring 4 x 4 inches folded twice, at the end of the procedure.

Data collection

Physicians who performed the abdominal paracentesis recorded data, including demographic data (gender, age, underlying disease), type of physician (residents, fellows or staffs), use of ultrasound guidance, efficacy (number of attempts, repositioning, and ascites flow) and traumatic tapping. We recorded other complications (ascites leakage, abdominal wall hematomas and peritonitis) on the first day after the procedure by telephone interview. For inpatients, information was collected by the ward physician.

Outcome measurement

The primary outcome was efficacy, which included the number of times the needles needed repositioning, number of attempts, ascites flow rate, and failure rates. Secondary outcomes included complications such as traumatic tapping, ascites leakage, abdominal wall hematomas, and peritonitis.

"Attempt" was defined and counted as a number of times that the needle was inserted forwardly until it was withdrawn backward. "Failure" was paracentesis in which no peritoneal fluid was collected. "Traumatic tapping" resulted in initial bloody ascites which gradually cleared, or gross blood at the puncture site which formed a clot after awhile. "Ascites leakage" resulted in changing of the gauze dressing once or more. "Repositioning" was defined as a changing the needle's position after the initial flow ceased. "Abdominal wall hematoma" was defined as a discoloration of skin at the area of abdominal paracentesis (area of discoloration was measured in diameter). "Peritonitis" was diagnosed in case of fever, abdominal pain, peritoneal fluid polymorphonuclear cell count more than 250 /mm3 and the previous ascites profile was normal.

Statistical analysis

All analyses were performed with SPSS for windows (SPSS Inc., an IBM, Chicago, Illinois, USA). For continuous variables, *e.g.* age and flow rate, unpaired t-test was used to compare the means between disposable needle and angiocath needle groups. Chisquare test and Fisher-exact test were used to assess the differences of proportion of categorical variables between disposable needle and angiocath needle groups. Statistical significance was judged by a 2-tailed p-value of less than 0.05.

This study was approved by Siriraj Institutional Review Board.

Results

A total of 200 patients were assigned to disposable needle group (100 patients) or angiocath needle group (100 patients). The baseline characteristics of the patients were similar (Table 1).

The primary and secondary outcomes of the two groups were compared. The disposable needle group had significantly fewer attempts, a lower failure rate and fewer abdominal wall hematomas than the angiocath group. The disposable group had less traumatic tapping, although the data difference was statistically insignificant. However, the ascites flow rate

Table 1. Demographic data

Characteristics	Disposable needle (n = 100)	Angiocath $(n = 100)$	p
Age (years), mean ± SD	60.7 ± 10.8	57.3 ± 13.4	0.055
Female, n	52	44	0.258
Operator, n			
Resident	47	55	
Fellow	45	41	0.342
Staff	8	4	
Diagnosis, n			
Cirrhosis <u>+</u> hepatocellular carcinoma	67	65	
Malignancy without cirrhosis	19	27	
Nephrotic syndrome	1	0	0.443
Portal vein thrombosis	1	1	
Others*	12	7	
Ultrasound-guidance, n	53	53	1

^{*}Other diagnosis included amyloidosis (2 cases), tuberculous peritonitis (2 cases), hepatic failure (2 cases), secondary peritonitis (4 cases), chronic kidney disease (4 cases), unknown (5 cases)

Table 2. Efficacy and complications

Outcomes	Disposable needle $(n = 100)$	Angiocath needle $(n = 100)$	p
Efficacy			
Attempt			
1 attempt, n	97	84	0.006
> 1 attempt, n	3	16	
Failure, n	0	6	0.013
Repositioning, n	33	46	0.081
Flow rate (ml/min)	53.1 ± 26.8	67.3 ± 49.1	0.012
Complications			
Traumatic tapping, n	3	9	0.134
Leakage, n	3	2	1
Hematoma, n	1	8	0.035
Peritonitis, n	0	0	1

in the angiocath group was significantly greater than that of the disposable needle group (Table 2).

Discussion

Therapeutic abdominal paracentesis is a common medical procedure. To search for better and less expensive devices or techniques will certainly improve the cost-effectiveness of the procedure. Results of the present study favored the disposable needle because it provided greater efficacy (fewer attempts, less failure and required less repositioning) and reduced complication rates (fewer abdominal wall hematoma),

while the angiocath needle provided greater ascites flow rate.

The present study demonstrated the higher rate of single attempt success and lower failure rate by the disposable needle compared to angiocath needle. The reason is unclear. The amount of ascites may not be the factor because all studied patients had moderate to marked ascites and half of them were performed under US-guidance (due to the prefer of some operators *i.e.* Gastroenterology fellows, not because of the small amount of ascites). The authors postulated that the problem with angiocath needle may be in the

procedural steps. During the insertion of the angiocath through the abdominal wall, the stylet is always kept inside the catheter until the catheter enters peritoneal cavity as recognized by seeing the ascites coming into the stylet. Then the stylet was withdrawn and the catheter is then inserted forwardly without stylet. In the authors' opinion, this step can accidentally cause kinking of the catheter at the level of skin or inside the abdominal wall and might explain the higher failure rate of angiocath needle than the disposable needle.

The present study confirmed the very low rate of the serious complications of therapeutic paracentesis with disposable needles, which were hematoma in 1 patient and none with peritonitis. These numbers are comparable to the complication rates reported in the literature using multi-hole or plastic needles, which were 1% for hematoma and 0.4% for peritonitis^(7,8). On the other hand, angiocath needles turned out to have more abdominal wall hematoma (8%) than disposable needles (1%) and more than the usual rate (1%). This might be explained by the larger size of the angiocath needle compared to disposable needle. Although the chance of having more patients with bleeding disorders in the angiocath group could not be excluded because we did not check the platelet count and coagulogram of patients in both groups routinely. Nevertheless, the present study showed no evidence that angiocath needles were safer than disposable needles, and confirmed the result of the study by Runyon et al that metallic needle is safe for this procedure⁽⁶⁾. Furthermore, disposable needles have the advantage of lower cost, a difference of 21 baht per needle (costs in Siriraj Hospital in 2010).

Although the present study showed that the flow rate of ascites release was slightly slower with disposable needles than angiocaths, this can be explained straightforwardly by noting the bigger diameter of the angiocath (No. 16) compared to disposable needle (No. 18). The reason the authors decided to compare these 2 needles with different sizes in the present study is because in the real practice, angiocath No. 16 and disposable needle No. 18 are the 2 most commonly used needles since they represent the best of each side. Nevertheless, the authors calculated the duration for a large-volume paracentesis (5 liters) by the mean time used and found that the time difference between the 2 needles will approximately be 20 minutes, which is of unclear clinical significance. By contrast, physicians may prefer the disposable needle because it needs fewer repositions by the physicians, which then also requires another pair of sterile gloves and even another paracentesis set.

There are some limitations of the present study. First, it is not a randomized controlled study as the authors had previously planned because the physicians who performed paracentesis did not feel comfortable in using the needles they were not familiar with. Thus, the authors allowed the physicians to choose the type of needle they preferred. However, demographic data showed no statistically significant difference between both groups. In fact, the authors believe that those who performed the procedures chose that particular type of needle because they were competent or felt confident in using it, or preferred it because they had used it in the past. This would reduce confounding factors regarding expertise or skill in performing the procedure. Second, some data collection process regarding the late complications of the procedure was completed by telephone interview. Since the authors interviewed the patients one day after the procedure, it was possible that some information might be mistakenly recorded. Moreover, although there was no peritonitis in our study, it might have been too early to detect this complication after only one day.

In conclusion, disposable needles used for therapeutic abdominal paracentesis have definite advantages over angiocath needles such as fewer attempts, fewer complications and reduced cost, but at the cost of a slower ascites flow rate.

Potential conflicts of interest

None.

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ประสิทธิภาพของเข็มแบบใช[้]ครั้งเดียวทิ้งกับเข็ม angiocath ในการเจาะระบายสารน้ำในช[่]องท[้]อง เพื่อการรักษา

ดุษฎี โชคซัยเจริญศรี, อาทิตย์ อรัญญาเกษมสุข, สุพจน์ พงศ์ประสบชัย

ภูมิหลัง: เข็มแบบใช[้]ครั้งเดียวทิ้งและเข็ม angiocath เป็นเข็มที่มีการใช[้]บอยที่สุดในการเจาะระบายสารน้ำในท[้]อง เพื่อการรักษา การศึกษานี้มีวัตถุประสงค์เพื่อเปรียบเทียบประสิทธิภาพ และภาวะแทรกซ้อนระหว[่]างเข็มทั้งสองชนิดนี้ ในการเจาะระบายสารน้ำในท[้]องเพื่อการรักษา

วัสดุและวิธีการ: การศึกษานี้เป็นแบบ open-label ในผู้ป่วยที่มีข้อบงชี้ในการเจาะระบายสารน้ำในท้อง เพื่อการรักษา ในโรงพยาบาลศิริราชตั้งแต่เดือนมิถุนายนถึงเดือนธันวาคม พ.ศ. 2552 ผู้ป่วยได้รับการเลือกใช้เข็ม แบบใช้ครั้งเดียวทิ้ง (เบอร์ 18) หรือเข็ม angiocath (เบอร์ 16) โดยแพทย์ผู้เจาะแล้วเปรียบเทียบประสิทธิภาพ และภาวะแทรกซ้อน ผลการศึกษา: มีผู้ป่วยที่ใช้เข็มแบบใช้ครั้งเดียวทิ้ง 100 ราย และเข็ม angiocath 100 ราย กลุ่มที่ใช้เข็มแบบใช้ครั้งเดียวทิ้งสามารถเจาะน้ำได้ภายในเพียงครั้งเดียวมากกว่า (ร้อยละ 97 เทียบกับร้อยละ 84, ค่าพี = 0.006) เจาะไม่สำเร็จน้อยกว่า (0 เทียบกับร้อยละ 6, ค่าพี = 0.013) แต่อัตราการใหลของสารน้ำในกลุ่ม angiocath เร็วกวาเข็ม แบบใช้ครั้งเดียวทิ้ง (67.1 มล./นาที เทียบกับ 53.1 มล./นาที, ค่าพี = 0.012) เข็มแบบใช้ครั้งเดียวทิ้งเกิดภาวะแทรกซ้อน น้อยกวาโดยเฉพาะ hematoma ที่ผนังหน้าท้อง (ร้อยละ 1 เทียบกับร้อยละ 8, ค่า พี = 0.035) และการเจาะได้เลือดปน (ร้อยละ 3 เทียบกับร้อยละ 9, ค่าพี = 0.134)

สรุป: เข็มแบบใช[้]ครั้งเดียวทิ้งมีประสิทธิภาพในการใช[้]เจาะระบายสารน้ำในช[่]องท[้]องเพื่อการรักษาดีกว[่]าเกิดภาวะ แทรกซ[้]อนน[้]อยกว^{่า} แต[่]มีอัตราการไหลของสารน้ำช[้]ากว^{่า}