Real-time ultrasound guided spinal anesthesia versus conventional technique for orthopedic knee surgery: a randomized controlled trial

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Abstract

Background: Ultrasound imaging skills are valuable for enhancing the safety of different puncture techniques supported with the fact that the developments in imaging quality have significantly improved our understanding of spinal sonoanatomy. Today, ultrasound imaging has been used to assist or guide central neuroaxial blocks, however, the data about the use of real time guided ultrasound neuroaxial blocks are scanty. The study aimed to identify the value of using the real time ultrasound guidance in applying spinal anaesthesia when compared with the conventional landmark guided approach, regarding the efficiency of the anesthetic technique and incidence of associated common complications. Methods: This randomized controlled trial included 178 patients scheduled for elective Knee orthopedic surgeries under spinal anesthesia in El Kasr Al-Aini Hospital, Cairo University were enrolled in the study. Patients were randomly assigned into conventional group in which 89 patients received landmark guided paramedian spinal anesthesia and ultrasound group in which 89 patients received real time ultrasound guided paramedian spinal anesthesia. Results: The mean numbers of puncture attempts, levels and needle redirections between the conventional group and ultrasound group were 1.61±0.83 vs. 1.12±0.36 (p=0.013), 1.15±0.36 vs. 1.06±0.25 (p=0.018) and 2.68±2.75 vs. 1.94±1.93 (p=0.021) respectively. Ultrasound guided group of patients showed significant lower incidence of bloody puncture and paraesthesia after engaging the needle through the dura. Conclusion: Real time ultrasound guiding improved the ease of introducing spinal anesthesia, reduced the number of puncture attempts, number of puncture levels, number of needle redirections, and incidence of complications.

Background

Spinal anesthesia is a wide spread popular method of anesthesia, used for most of the orthopedic surgical procedures involving the lower limb [1]. Spinal anesthesia remains the first choice in such surgeries because of its dense block, rapid onset, low infection risk as from catheter placement in cases of epidural, avoidance of serious complications that may be associated with airway management during general anesthesia, in addition to other benefits associated with central neuroaxial blockade (e.g. decreased incidence of blood loss, thromboembolism and wound infection) [2].

Spinal anesthetic block failure among experienced anesthetists reported to be not more than 1% [3], however such incidence could be higher in a training environment due to the inability to predict technical difficulties or placing needle accurately with any of the landmark-based techniques. This may lead to multiple needle attempts, block failure, discomfort, poor patient satisfaction and occurrence of complications [4].

Such failure may be related to improper technique, inexperience (of the unsupervised trainee especially), and inability to appreciate the need for a meticulous approach [5].

Minimizing the incidence of failure is an important pre-requisite for gaining the benefits of spinal anesthesia, and to prevent the potential pitfalls [3]. The use of ultrasound guidance for performing

regional anesthesia is a relatively new and evolving concept, though it was first reported in 1980 [6]. Ultrasound allows real time imaging of neural structures, without either staff or patient exposure to radiation.[7] Ultrasound-imaging skills are valuable for enhancing the safety of different puncture techniques especially with the developments in imaging quality that have significantly improved our understanding of the sonoanatomy of the lumbar spine. [8]

Today, ultrasound imaging has been used to assist or guide central neuraxial blocks if an interlaminar window that permits passage of sound waves into the vertebral canal can be identified, the same window will permit passage of a needle into the epidural or intrathecal space [9]. This coupled with real-time imaging of the needle passage to the required sites should permit high-quality and low-risk regional anesthesia. [10]

It was reported that ultrasound guided epidural needle insertion had reduced the number of puncture attempts [11–14], reduced the need for multiple levels puncture [12–14] and improved patient satisfaction during the procedure [13], for these advantages it was recommended by the National Institute of Clinical Excellence (NICE) in the United Kingdom to recommend that ultrasound guided epidural blocks should be routinely used. [15]

Our aim in this study was to investigate efficacy and safety of real-time ultrasound guided paramedian sagittal neuroaxial approach in providing spinal anesthesia for pelvic and lower extremities orthopedic surgeries in comparison to the conventional landmark guided midline approach.

Methods

After obtaining Institutional Ethical Committee approval and written informed consent, 178 patients ASA I/II scheduled to undergo elective Knee orthopedic surgeries under spinal anesthesia in El Kasr Al-Aini Hospital, Cairo University were enrolled into this prospective randomized controlled study, excluding patients with age less than 18 and more than 60 years, Body mass index more than 30, uncooperative patients and those with known coagulopathy. The study adheres to CONSORT guidelines.

Patients were randomized using opaque sealed envelope after enrolment into two groups, ultrasound group (group US n = 89) and conventional group (group C n = 89). Numbers in the envelope were generated by a computer-generated randomization (www.randomization.com).

Upon arrival to the operating theatre, analgesia will be given in form of fentanyl IV (0.5 ug/kg) only for those in pain associated with positioning, measurements of the baseline hemodynamic parameters will be recorded. All patients will be monitored intra-operatively using: an ECG, non-invasive blood pressure, and pulse oximetry. An infusion of a crystalloid solution will be started as a bolus of 500 ml in 10 min.

In the two groups, Patients were helped to maintain a sitting position on a leveled trolley with their feet comfortably rested. A pillow was given to hug and patients were asked to sustain an arched posture with

the help of an assistant to maintain positioning. Sedation was avoided before or during carrying out spinal anesthesia.

In group (C): After positioning, landmarks were palpated and a 4-point scale varying between easy, moderate, difficult and impossible, was used to assess the ease of palpation. After palpating spinous processes in the midline, an interspinous space was selected with preference of the anesthesiologist and a mark 1.5 cm lateral and caudal to the center of the selected space was identified to spot the paramedian access. Then with strict aseptic technique including scrubbing and preparing the skin with povidone iodine, a 2 mL of 1% lidocaine was used to infiltrate the skin. A 25G whitacre spinal needle was directed medially and slightly cephalad to access the space selected in the paramedian approach with no restriction for the angle of insertion or depth reached, but with simultaneous record of the data awaited in our hypothesis. After successful puncture flagged by free flow of cerebrospinal fluid (CSF), preferred dose of local anesthetic was injected for spinal anesthesia followed by aiding the patient for desired operative position and testing the block by cold discrimination till achievement of the preferred level. In case of failure, the patient was aided to set in-order to perform the matched technique (an US guided paramedian technique) as mentioned later on. And in case of repeated failure, general anesthesia was conducted.

In group (US): After palpation of the landmarks, then using the SIEMENS (Acuson S2000) ultrasound system. The curved array low frequency transducer (2−5 MHz) was used for the scan to allow for deeper acoustic visualization. Generous amount of US gel was applied to the skin over the lumbar and sacral regions for acoustic pairing. A (pre-intervention scan) was performed combined with optimization of the view by adjusting appropriate depth and gain. The transducer was positioned longitudinally 1−2 cm lateral and parallel to the spinous processes reflecting the long axis of the vertebral column, with its orientation marker directed cephalic, also tilted slightly medially during the scan, so that the US beam is insonated in a paramedian oblique sagittal plane. The sacrum was identified by scanning caudally while still maintaining unchanged angulation. It was identified as a flat hyperechoic band with an anechoic shadow anteriorly. The bony spinous process appeared as a hyperechoic white convex rim with a deep anechoic shadow. The concavity or gap between the sacrum and the lamina of L5 was the L5/S1 intervertebral space. Identification of the L3/L4 and L4/L5 intervertebral spaces was done consequently by counting upwards. Finally the transducer was positioned over the L3/L4 and L4/L5 intervertebral spaces.

This position of the transducer was marked on the patient's back using a skin marking pen in order to ensure that the transducer was placed on the same position after sterilization made before the intervention, also to avoid the need to repeat the guide scan done to identify the L3/4 or L4/5 intervertebral space as described above. The transducer was prepared by smearing a thin layer of US gel on its outline and covering with a sterile-transparent dressing ensuring that no air was trapped between the outline and the transparent dressing. No gel was applied directly to the skin over the area scanned as there were no data demonstrating the safety of US gel on central neuroaxial structures, but it was replaced by saline as a substitute coupling agent. Fine adjustments to the settings mentioned before were required to excel the slight deterioration in the quality of the US image lacking the US gel on the skin.

Local anesthetic (lignocaine 1%) 2–3 ml was infiltrated to the skin at the caudal end of the probe. The 25G whitacre spinal needle was inserted in plane of the US transducer from the caudal end while maintaining a long axis relation with its tip directed towards the targeted interlaminar space (L3/L4 or L4/L5) which was always maintained centered on the US image. The angle of needle insertion was adjusted according to the real-time US guidance. The needle was advanced to the interlaminar space, till visualizing the engagement with the ligamentum flavum followed by the dura. Once a free flow of CSF is determined, anesthetic management was continued as mentioned before, with the alternative of introducing the (conventional landmark technique) in case of failure.

Our primary outcome was the difference in number of puncture attempts (the separate insertion of the needle through the skin) between the 2 groups needed till successful dural puncture which was noted by free flow of CSF, secondary outcomes were Landmark palpation easiness score using a four point scale [16], the visibility of the ligamentum flavum-dura mater complex by the US using a four point numerical scale [17], duration of the anesthetic procedure(the time from the handling the needle till completion of injection), number of needle redirections and puncture attempts, the incidence of paraesthesia and backache, the incidence of failure of introducing spinal anesthesia using each of the study techniques, patient's satisfaction score regarding the anesthetic technique using a three point scale 0–2 in which (0 = dissatisfied, 1 = somewhat satisfied, 2 = satisfied), and post dural puncture headache (incidence-onset-duration-severity).

The ease of landmark palpation (palpation of the iliac crests and spinous processes) was graded on a four point scale [16]:

- Easy = light palpation of iliac crests, spinous processes identified sight.
- Moderate = light to deep palpation of iliac crests, light palpation of spinous processes.
- Difficult = deep palpation of iliac crests and spinous processes.
- Impossible = iliac crests or spinous processes could not be palpated.

The visibility of the ligamentum flavum-dura mater complex by the US was graded using a four point numerical scale [17] (0: not visible, 1: hardly visible, 2: well visible, 3: very well visible). Time for marking the anatomical access: in group C was defined as time from which the anesthesiologist start palpating to identify the landmarks till marking the skin, In group US it was defined as time from which the ultrasound probe is placed on the skin till the anesthesiologist declare that the markings is completed.

Sample size calculation was done using the comparison of number of puncture attempts till successful dural puncture, as it is the primary outcome of our study. As reported in previous publication [18], the mean ±SD of number of attempts in ultrasonographic guided approach was approximately 1.28±0.7 times, while in conventional technique it was approximately 1.98±1.66 times. Accordingly, we calculated that the minimum proper sample size will be 89 patient in each group to be able to detect a real difference of 0.7 times with 80% power at α = 0.05 level using Student's t-test for independent samples.

Sample size calculation was done using MedCalc statistical software version 16.2.1 for MS Windows, MedCalc bvba, US.

Data were described statistically in expressions of mean ± standard deviation (± SD), median and range, or frequencies (number of patients) and percentages when appropriate. Comparison of numerical variables between the study groups has been done using Student t test for independent samples in comparing 2 groups when normally distributed and Mann Whitney U test for independent samples when not normally distributed. In order to compare categorical data, Chi square (χ^2) test has been performed. Same test has been used as an alternative when the expected frequency is less than 5. A probability value (p value) less than 0.05 is considered statistically significant. All statistical calculations were done using computer programs Microsoft Excel 2007 (Microsoft Corporation, NY, USA) and SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) version 15 for Microsoft Windows.

Results

The study included 129 males and 49 females All patients received the allocated intervention, no patients were lost to follow-up, and data acquirement was complete, only one patient in group US received general anesthesia after spending more than three operative hours and retrieval of sensation. There was no statistical difference between the two groups as regard sex, age, height, body mass index (BMI) (table 1).

Table 1: Demographic data presented as either frequency (%) or mean±SD

	Group C (n=89)	Group US (n=89)	p value
Sex			
male	74.2%	70.8%	0.615
female	25.9%	29.2%	
Age (years)	31.3±9.4	30.1±8.6	0.210
Height (m)	1.7±0.07	1.7±0.06	0.257
Body mass index (kg/m^2)	26.1±2	26.5±1.5	0.226

Using the four point landmark palpation scale for assessing the easiness in the two groups, showed no incidence for 'impossible' grade in either of the two groups patients and showed a higher frequency for 'easy' grading in group C while group US showed higher frequency for 'moderate' grading. This difference was statistically significant (p < 0.01) (Fig 1).

There was statistically significant difference between the two groups regarding the marking time and the anesthetic procedure duration which were longer in Group US as shown in table 2.

Table 2: Times recorded presented as mean ± SD

	Group C (n=89)	Group US (n=89)	p value
Marking time (sec.)	55±25.3	178.1±54.1	0.012
Anesthetic procedure Duration (sec.)	136.4±83.2	138.3±63.4	0.001

Compared to control group, Ultrasound guided group of patients showed statistically significant lower number of puncture attempts, lower number of puncture levels and lower number of needle redirections as shown in table 3.

Table 3: Number of levels, attempts, redirections noted presented as mean ± SD

	Group C (n=89)	Group US (n=89)	P value
Needle redirections	2.68±2.75	1.94±1.93	0.021
Needle attempts	1.61±0.83	1.12±0.36	0.013
Number of levels	1.15±0.36	1.06±0.25	0.018

Compared to control group, ultrasound guided group of patients showed significantly lower incidence of bloody puncture and paraesthesia after engaging the needle through the dura as shown in table 4. Postdural puncture headache incidence was recorded once in each group with no statistical significance difference.

Table 4: Complications noted presented as frequency (%)

	Group C (n=89)	Group US (n=89)	p value
Bloody puncture	37 (41.6%)	8 (8.9%)	0.012
Paraesthesia	35 (39.3%)	9 (10.1%)	0.026

The ultrasound guided patients' group showed significant higher values of satisfaction score in comparison to the control group of patients as shown in figure 2.

There was a high correlation between BMI and number of attempts in Group C with Pearson correlation coefficient (r = 0.58, p value = 0.04) (fig 3). While in Group US; no correlation was detected with Pearson correlation coefficient (r = 0.19, p value = 0.13) (fig 4).

By applying the receiver operating curve (ROC) to detect a cut off value of BMI for prediction of more than one attempt in the two study groups:

Analysis of ROC in Group C; BMI at 26.5 was statistically significant in predicting for more than one attempt by sensitivity of 64% and specificity of 62% with AUC of 0.66 and p value was (0.01) as shown in figure (5).

Analysis of ROC in Group US; BMI at 26.5 was nearly statistically significant in predicting for more than one attempt by a slightly higher sensitivity than group C (70%) and mush lower specificity than group C of (44%) with AUC of 0.56 and p value was (0.08) as shown in figure (6).

Discussion

In this study we found that real time ultrasound guided spinal anesthesia, decreased the number of puncture attempts, number of puncture levels, number of needle redirections, and incidence of complications, and also increased the patient's satisfaction towards that anesthetic procedure when compared to conventional landmark guided blind technique.

Unfortunately no previous randomized controlled trials were done to attest the real time guided technique in order to compare its role in improving the quality of applying spinal anesthesia with the conventional blind method through and to the best of our knowledge; our study is the first randomized controlled study to compare real time ultrasound technique to conventional manual palpation blind method.

Conroy et al [18] who used real time ultrasound guided spinal anesthesia among a series of 100 patients undergoing lower limb orthopedic surgery in order to measure the success rate of CSF acquisition, which was later efficaciously acquired in 97 out of the 100 patients.

Lee et al [19] who tested real-time ultrasound guided spinal anesthesia in the prone position for 10 patients undergoing knee arthroplasty in an effort to positively attain CSF through this approach, they reported successful spinal anesthesia in all applicants; and they recorded that nine patients needed only one attempt to acquire CSF. A weakness of this study was the small number of patients involved, the lack of a control group and the need for prone positioning of patients for that technique which was problematic.

These trials support our findings, as we demonstrated that ultrasound guided group of patients when compared to the control group showed significant lower number of puncture attempts (1.12±0.36 vs. 1.61±0.83) lower number of puncture levels (1.06±0.25 vs. 1.15±0.36) and lower number of needle redirections (1.94±1.93 vs. 2.68±2.75).

In the current study, ultrasound guided group of patients significantly showed lower incidence of bloody puncture and paraesthesia after engaging the needle through the dura. Postdural puncture headache

incidence was recorded once in each group with no statistical significance difference between the two groups.

In accordance with our study, the meta-analysis [20] concerned with the use of ultrasound as a preprocedural guidance, concluded that ultrasound imaging reduced the risk of traumatic procedures with a risk ratio of 0.27 (95% confidence interval 0.11 to 0.67, P = 0.005) with an absolute risk reduction of 0.059 and reduced the odds of a traumatic procedure (0.28 (0.13 to 0.61), P = 0.001).

On validating a correlation between BMI and number of attempts in our study, there was a high correlation in Group C while in Group US; no correlation was detected and by applying the receiver operating curve (ROC) to detect a cut off value of BMI for prediction of more than one attempt in the two study groups; BMI at 26.5 was nearly statistically significant in predicting for more than one attempt by a slightly higher sensitivity in group US than group C (70% ⬜ 64%) and mush lower specificity in group US than group C (44% ⬜ 62%). This correspondence indicates a value for using ultrasound guidance in groups of patients with higher BMI.

This clarification is braced by the conclusions of Chin and colleagues [21] who studied preprocedural ultrasound screening in patients with difficult surface anatomic landmarks (obese patients, patients with spinal deformities, and patients with previous spine surgery), to attest its role in improving the easiness of performing a lumbar puncture, and they found that US preprocedural screening was associated by reduced number of passes to spinal needle insertion, there was a twofold difference between groups in the number of needle insertion attempts (group Ultrasound, 1 [1−2] vs. group Landmark, 2 [1−4]; P < 0.001) and number of needle passes (group US, 6 [1−10] vs. group LM, 13 [5−21]; P = 0.003).

Contrary to our study findings, Arzola et al [22] results differed from our study and most of the supporting studies; they attested using ultrasound preprocedural screening in aiding the introduction of epidural catheters in female patients going for normal labor, they found that ultrasound use didn't improve the easiness of lumbar epidural catheter, there was no difference in the median (interquartile range, IQR) insertion time of epidural between ultrasound and palpation groups [174 (120 to 241) as against 180 (130 to 322.5) s, in that order; P = 0.14], the number of interspace levels tried and needle passes were similar as well in both groups; this difference might be attributed to their special population as they selected parturient with effortlessly palpable lumbar spines.

Another study that reported a different finding than ours was conducted by Hayes et al in children [23], they tried to attest the value of using ultrasound scanning in identifying lumbar spaces in children, but they reported no benefit in using ultrasound when compared to manual palpation done by experienced anesthesiologist. This can be explained by the anatomical differences in pediatric population with relatively easy landmarks.

These different results from ours could be attributed for the diversity of techniques used rather than our real time method and also different reasons for failure in each of them, and so undeviating comparison was not possible.

Our study had a strength being done by a sole operator with moderate experience in the use of ultrasound this provides a degree of reliability that the difference in outcome between the two groups is not due to any difference in operator skills, this also provides the evidence that the use of ultrasound in this procedure is a skill that isn't hard to acquire.

Limitations: it is a single center study for a commonly performed technique also we didn't divide patients into subgroups according to factors that might affect degree of difficulty as some authors have done. It was not blinded the as the individual operator reported the study outcomes straight after performing the procedure, this supported the opportunity for observer bias.

Conclusion

Real time ultrasound guiding improved the ease of introducing spinal anesthesia, reduced the number of puncture attempts, number of puncture levels, number of needle redirections, and incidence of complications, in addition to increasing the patient's satisfaction towards that anesthetic procedure when compared to the conventional landmark guided blind technique.

List Of Abbreviations

ASA: American Society of Anesthesiologists

BMI: body mass index

CSF: cerebrospinal fluid

ECG: electrocardiogram

IL: Illinois, United States of America

IQR: interquartile range

IV: Intravenous

L5: Lumbar vertebra #5

NICE: National Institute of Clinical Excellence

NY: New York

ROC: Receiver operating curve

S1: Sacral vertebra #5

SD: Standard deviation

SPSS: Statistical Package for the Social Science

US: Ultrasonography

USA: United States of America

Declarations

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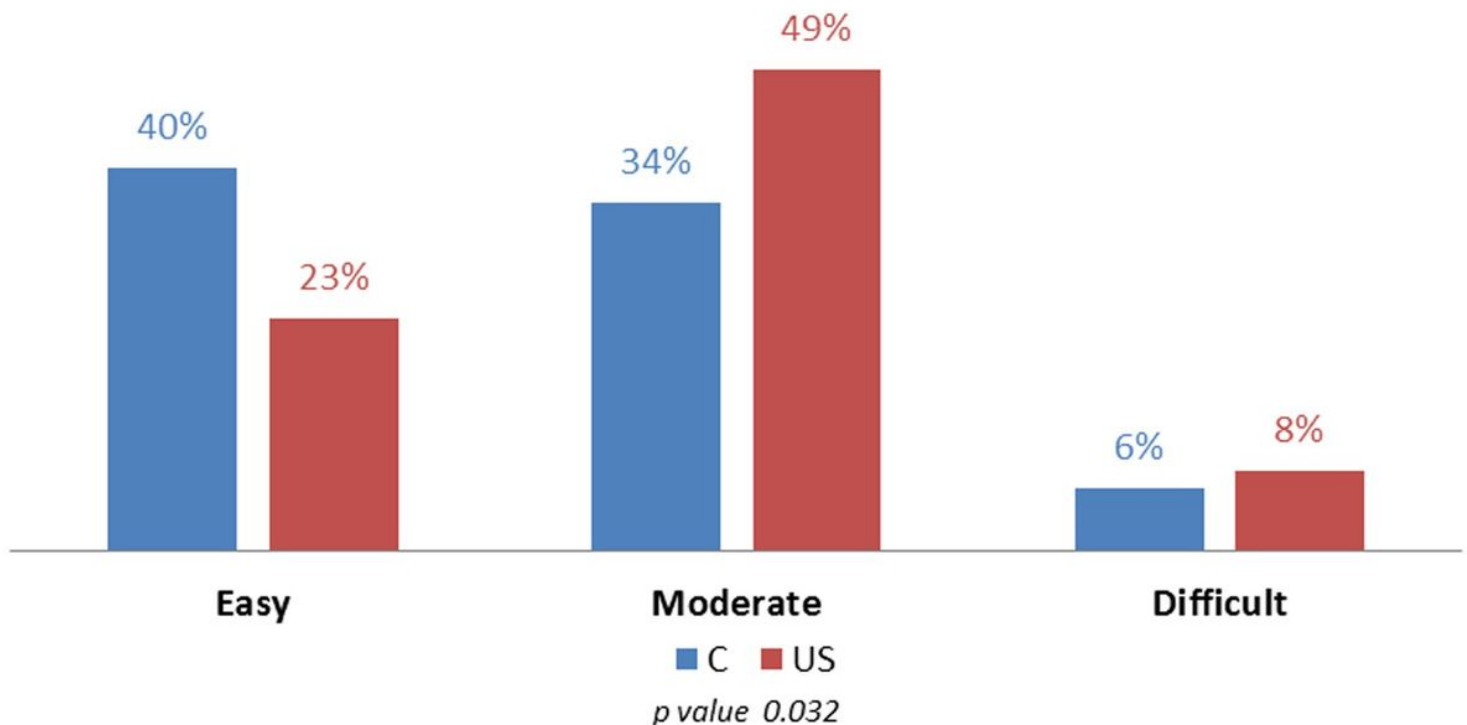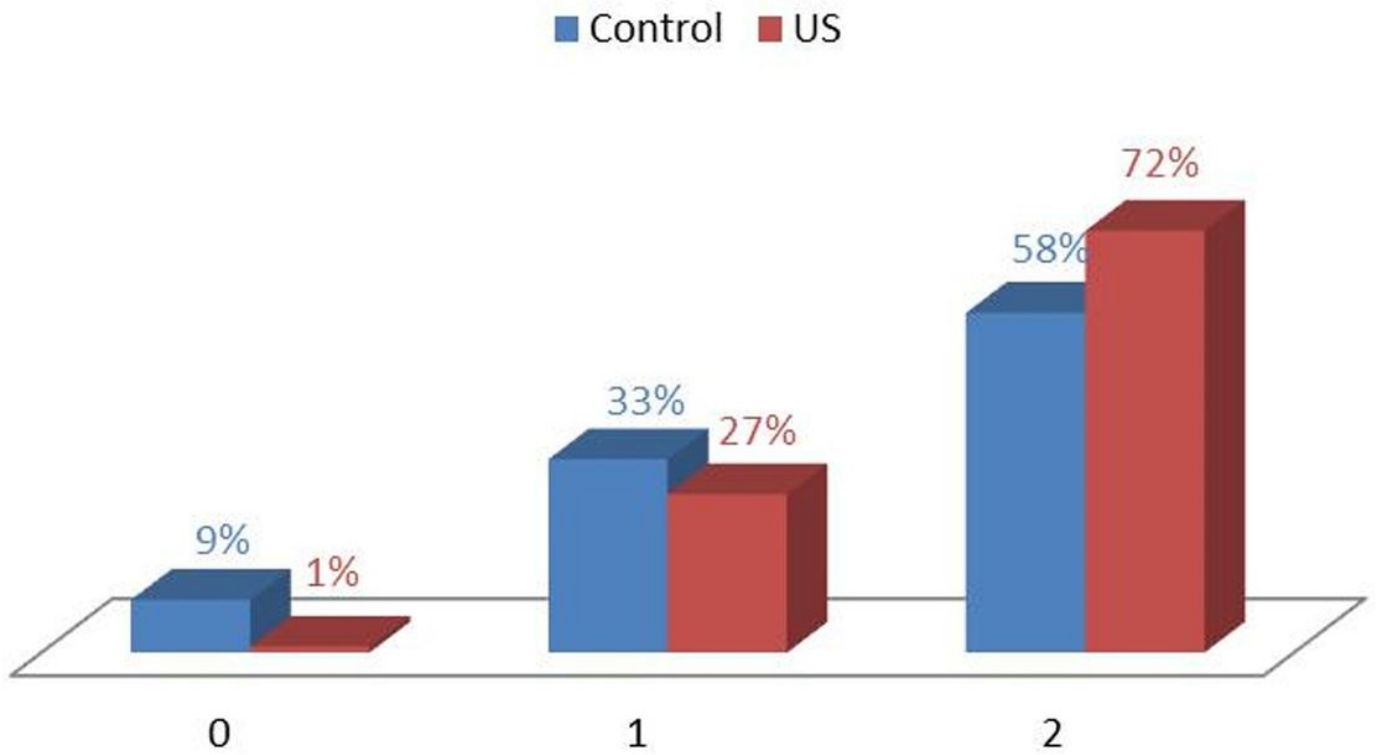
Figures

Figure 1

Figure 1: The difference in percentage of patients in each of the scale grades between the two study groups
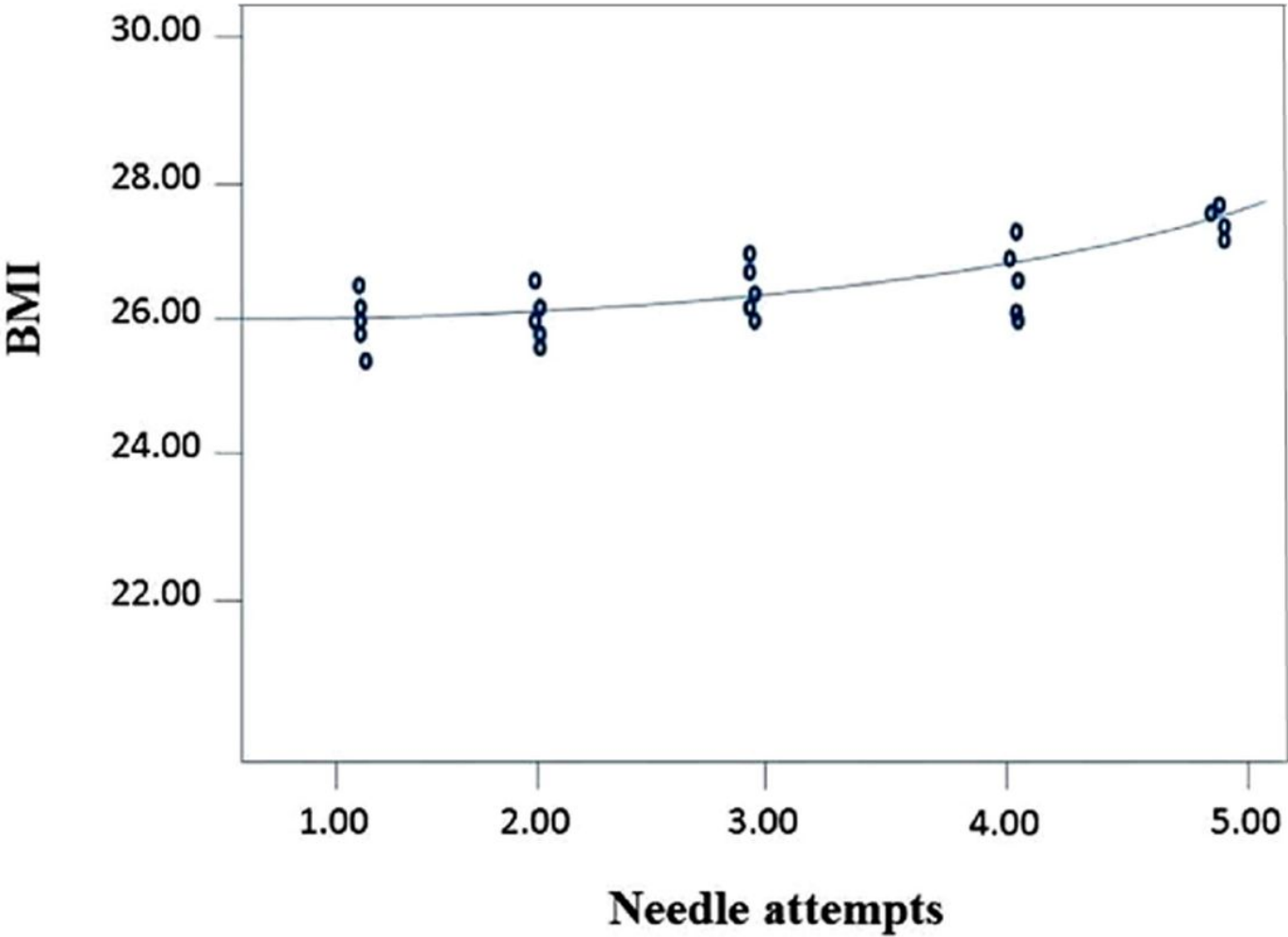
Satisfaction score

■ Control ■ US

Figure 2

Figure 2: The difference in percentage of patients in each of the satisfaction score grades between the two study groups
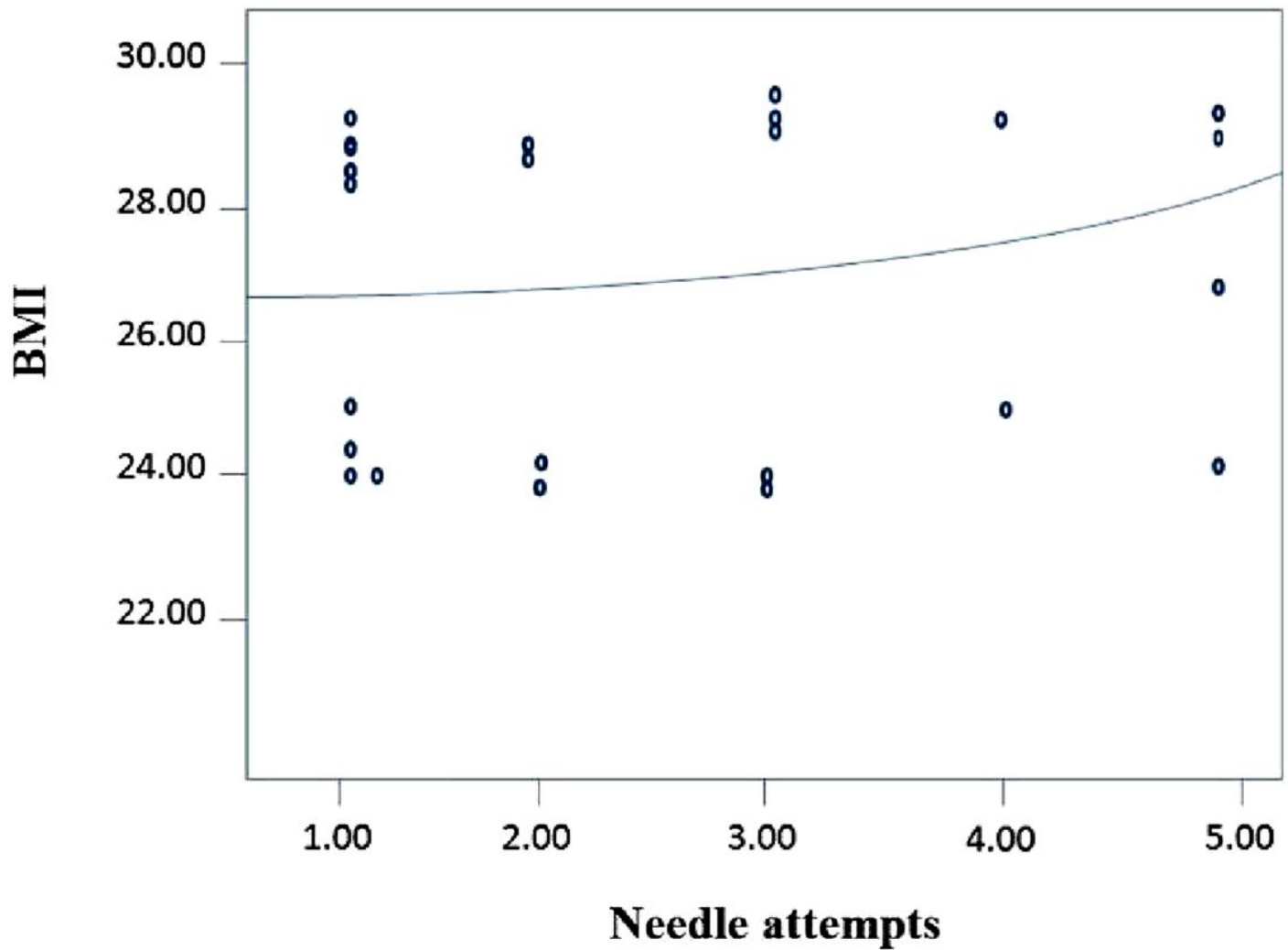
	Group C (n=89)
Pearson Correlation	0.04
R Sq Linear	0.58

Figure 3

Figure 3: scatter plot for correlation between BMI and number of attempts in Group C

	Group US (n=89)
Pearson Correlation	0.13
R Sq Linear	0.19

Figure 4

Figure 4: scatter plot for correlation between BMI and number of attempts in Group US
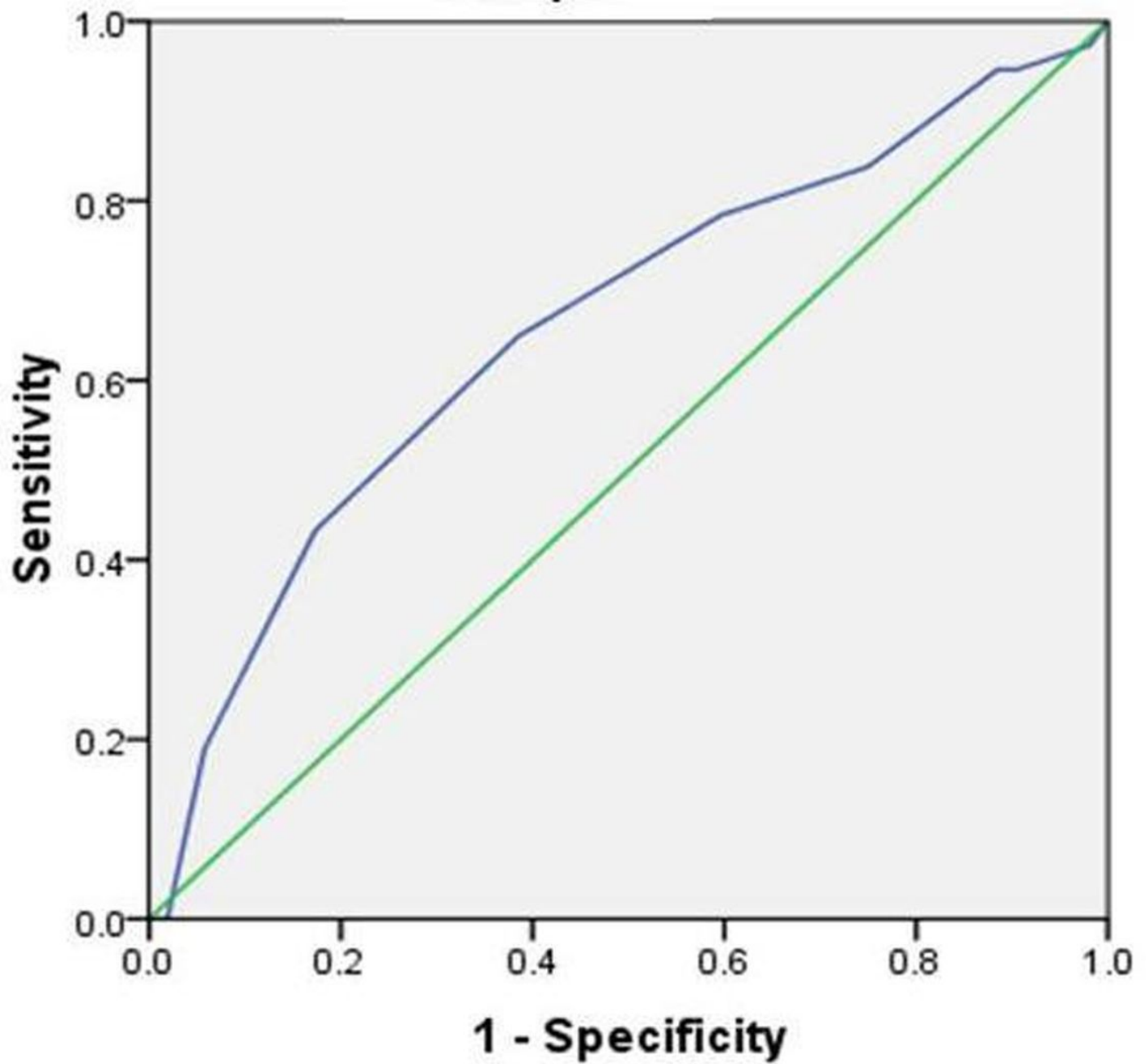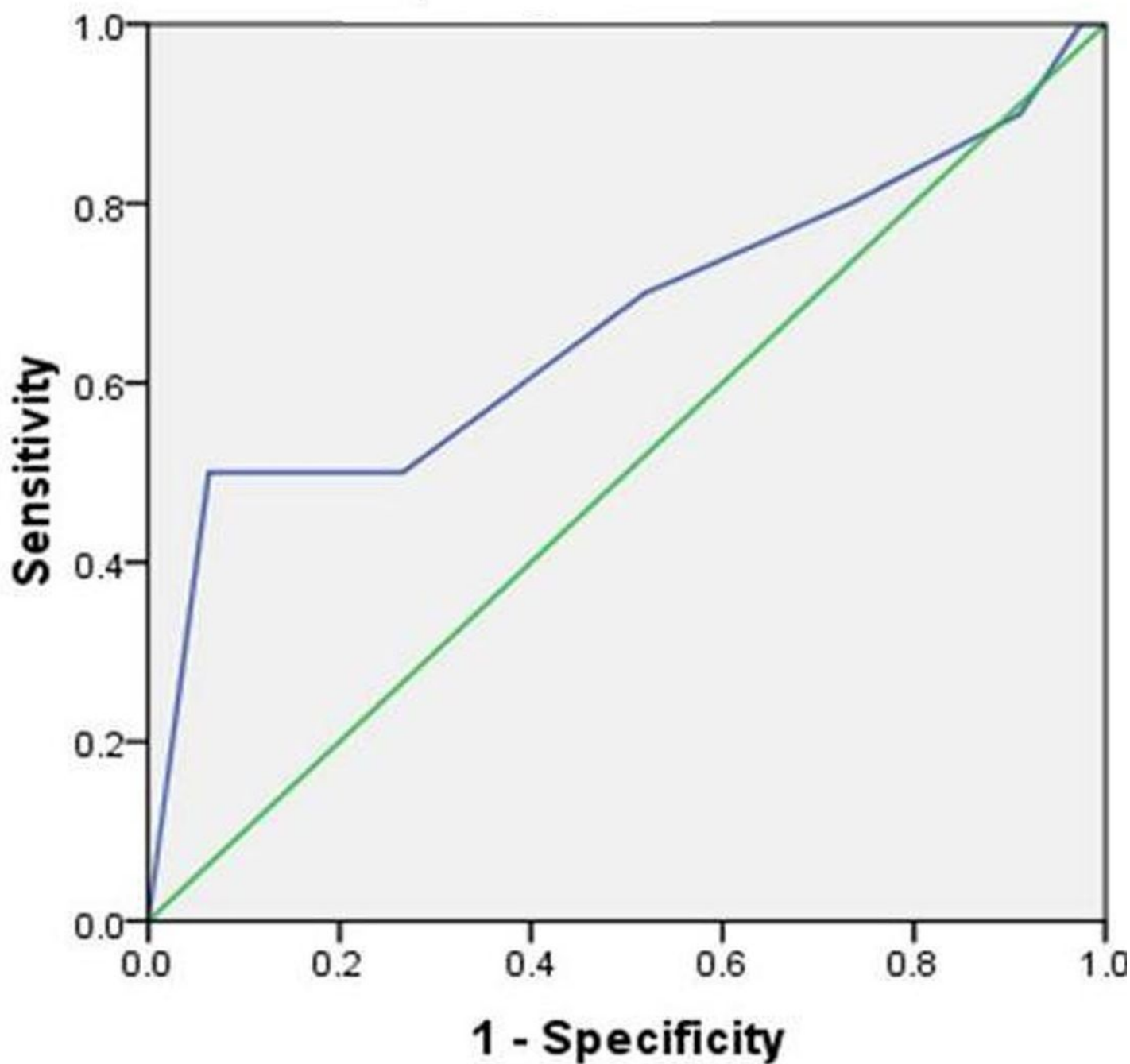
Area	Cut off value (BMI)	p value	Sensitivity	Specificity
0.66	26.5	0.01	64%	62%

Figure 5

Figure 5: ROC curve for correlating between BMI and incidence of more than one attempt in group

Area	Cut off value (BMI)	p value	Sensitivity	Specificity
0.56	26.5	0.088	70%	44%

Figure 6

Figure 6: ROC curve for correlating between BMI and incidence of more than one attempt in group US

Supplementary Files

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- CONSORTchecklist.doc