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A new predictive scoring system including shock index for unruptured tubal pregnancy patients

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Abstract

Objective: Shock index (SI) and predictive score grading system including it for predicting medical treatment failure of tubal pregnancies have been studied.
Study design: Eighty-eight patients were diagnosed as nonruptured tubal pregnancies. Shock index was calculated as the ratio of heart rate to systolic arterial pressure. A predictive score was used based on four parameters including initial level of β-human chorionic gonadotropin (βhCG), aspect of the image on ultrasound, size of the ectopic mass and shock index value at admission.
Results: Forty patients have undergone to surgery because of tubal gestational sac size ≥4 cm and/or presence of fetal heart activity. Nineteen patients were managed expectantly. Twenty-four patients received single dose methotrexate (MTX) and five patients received second dose MTX. Success rate for single dose MTX therapy was 72% (21/29). The cut-off shock index value for tubal rupture was 0.77 with 89% sensitivity and 61% specifity.
Conclusion: In this study, we demonstrated that tubal pregnancy patients who were managed with nonsurgical measures at admission and who had SI values lower than 0.77 and predictive score grades greater and equal to 6.5 did not experience tubal rupture and did not need surgical intervention during nonsurgical management.

Keywords: Shock index; Predictive score; Nonsurgical treatment; Success

1. Introduction

Although the availability of transvaginal ultrasound and β-human chorionic gonadotropin (βhCG) determination has increased, ectopic pregnancy (EP) still remains as one of the leading causes of maternal mortality. Tubal rupture may occur in 22–34% of ectopic pregnancies [1,2]. Physical examination, laboratory results and ultrasonographic evaluation cannot always establish the diagnosis of tubal rupture [3]. There remains patients who will benefit from nonsurgical treatment or will eventually need surgical intervention [4]. Systemic methotrexate administration; with possible serious side effects like bone marrow supression, dermatitis and stomatitis; to the patients has been proven to be successful in various studies and in one recent study performed by Barnhart and co-workers, only 0.5–1% of patients who received single dose MTX developed these side effects [4–8]. The single dose regimen was associated with fewer side effects [5,9]. Medical treatment proposal to the patients needs some objective criteria proven to predict tubal rupture during nonsurgical management [6,10]. Shock index (SI) as a ratio of heart rate to systolic blood pressure has greater value than traditional vital signs for prediction of emergency intervention need [11–13]. Elito et al. has developed a predictive scoring system including initial βhCG level, aspects of the image on the ultrasound, size of the mass and color Doppler for nonruptured ectopic pregnancies [6]. They observed color Doppler as the best significant parameter of this prediction system but they mentioned that it cannot be used alone. In

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this current study, color Doppler is substituted with SI and predictive value of this new predictive score grading system for tubal rupture has been evaluated.

2. Material method

This prospective cohort study was performed in the department of infertility and reproductive medicine at Zekai Tahir Burak Women's Health and Education Hospital from March 2003 to May 2004.

Eighty-eight patients were diagnosed as nonruptured tubal pregnancies (TP) and hospitalized according to the clinical and transvaginal sonographic examination. Patients, with any free pelvic fluid detected on transvaginal sonography revealing tubal rupture or tubal abortion, have been excluded at the beginning of this study with an attempt to define nonruptured TP patients and to observe their clinical course. Diagnosis of TP was based on symptoms like pelvic pain, amenorrhea, vaginal bleeding; physical examination findings like pelvic tenderness and palpable pelvic mass; quantitative βhCG value determination without any cut-off value for inclusion to the study; sonographic views like gestational ring with or without fetal heart beat and hematosalpinx revealing ectopic pregnancy on transvaginal ultrasound. Patients, with suspicious ultrasound view and clinical symptoms that precluded to establish an accurate diagnose of TP, were excluded from the study regardless of their βhCG values. Patients, with sonographic and/or clinical signs revealing tubal rupture or tubal abortion, were also excluded and TP size $\geq$4 cm and/or presence of fetal heart activity were surgically treated at admission. After exclusion of surgically managed 40 patients at admission; patients with βhCG levels <5000 mIU/ml and exhibiting a lowering pattern as much as 15% during a 24 h interval and who exhibited improvement of clinical symptoms and signs were expectantly treated. Patients; with hemodynamic stability and TP size of <4 cm and absent fetal heart activity and βhCG levels 5000–15,000 mIU/ml and with intact hepatic, renal, hematologic functions and without any sonographic view like free pelvic fluid and who did not exhibit a lowering βhCG pattern as much as 15% during a 24 h interval were treated with a single dose of MTX 50 mg/m^2 by IM injection. All medically treated patients, who showed clinical improvement and at least 15% decline between 4th and 7th day βhCG levels after administration of MTX on day 0, were followed as inpatient by weekly βhCG measurements until <10 mIU/ml levels were reached to decide treatment success. Patients, without at least 15% decline between 4th and 7th day βhCG levels, were reevaluated clinically and with transvaginal sonography whether any deterioration has exhibited or not and patients, without any clinical or ultrasound deterioration, were treated with second dose of MTX after this reevaluation. During nonsurgical therapies patients, who exhibited tubal rupture and/or hemodynamic unstability and/or increasing or plateauing βhCG levels despite two doses of MTX, received surgical intervention with laparoscopy or laparotomy.

At admission to the clinic; systolic arterial pressure (mmHg) and heart beat count per minute were measured for all patients included to the study. SI was also calculated as the ratio of heart rate to systolic arterial pressure. SI values between 0.5 and 0.69 were considered normal, 0.7–0.9 as subnormal and >0.9 as abnormal. βhCG measurements were studied with electrochemiluminescence immunoassay (ECLIA) method, Roche Elecsys 1010/2010. Transvaginal ultrasounds were performed with Toshiba Medical Systems, Powervision 6000 (5 MHz) by senior radiologists blind for the entire study.

Three groups of image aspect on ultrasound were considered as; live embryo, gestational sac ring and hematosalpinx. The greatest diameter of the mass was measured by ultrasound and classified according to the size as; small when the diameter was less than or equal to 25 mm, medium between 26 and 29 mm and large when the diameter was between 30 and 40 mm. βhCG levels <1500 mIU/ml was considered as favorable, 1500–5000 mIU/ml as borderline and 5001–15,000 mIU/ml as unfavorable for medical treatment success.

A predictive score grading system for predicting medical treatment failure with MTX for TP – first presented by Elito et al. – was used based on four parameters including initial level of βhCG that was measured at the time of diagnose, aspect of the image on ultrasound, size of the ectopic mass and shock index value at admission instead of vascular flow color Doppler that was one of the main parameters of the grading system used by Elito et al. Each parameter received grades from 0 to 2. Grade 0 was considered as unfavorable, grade 1 as borderline and grade 2 as favorable situation. Maximum grade was 8 and minimum was 0. The higher the predictive scores the higher the treatment success has been hypothesized. Clinical utility of this predictive score grading system including SI in stead of color Doppler for predicting nonsurgical treatment failure was evaluated. For nonsurgically evaluated patients at the beginning of the study, need for delayed surgery was considered as treatment failure and clinical and biochemical recovery without surgery was considered as treatment success. Statistical analysis was performed with SPSS 10.0 for Windows by using likelihood ratio, Student *t*-test, chi-square test, Fisher's exact test, ANOVA table, logistic regression analysis and a probability value of $p < 0.05$ was considered to be significant.

3. Results

The mean age of 88 patients included to the study was 29.9 ± 5.8 (18–46) years. The mean gestational age was 31 ± 22 days. Eight (9%) of 88 pregnancies were achieved by assisted reproductive techniques and 80 (91%) were spontaneous pregnancies. Thirteen (14%) patients have had previous TP experience. Forty patients have underwent to