A Research on Hidden Blood Loss in Laparpendoscopic Single-site Radical Hysterectomy and Pelvic Lymphadenectomy

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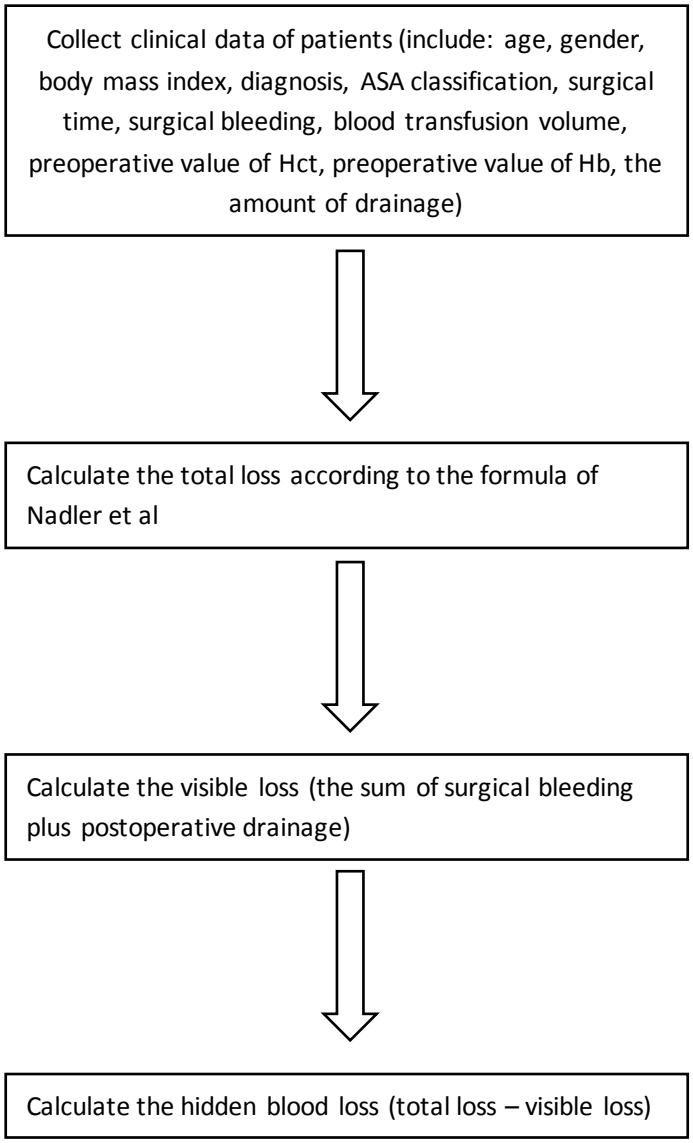
Study objectives The primary objective of this part is to evaluate the specific amount of hidden blood loss after laparoendoscopic single-site radical hysterectomy to treat patients with cervical cancer. The secondary objective of this study is to identify the risk factors of hidden blood loss using multiple linear regression analysis.

Trial design This is an retrospective cross-sectional observatory trial. After signing of informed consent, the electronic medical data of patients with cervical cancer who are treated with laparoendoscopic single-site radical hysterectomy will be analyzed retrospectively in this study. The blood loss during the procedure is recorded by anesthetists, including the blood in the suction bottle and in weighed compresses. The nurses also record the drainage volume as the post-operative blood loss before the remove of drainage tube. All patients have complete blood counts before the operation and on the second or the third post-operative day. And the hidden blood loss can be calculated according to Gross's formula. The risk factors of it can be identified using the multiple linear regression analysis. An overview of the study design is shown in Figure 1.



Sample size The planned sample size was based on data from a previous study, in which the standard deviation was 5. We assumed an one-tailed α error of 0.05 and a sampling error of 1.0. we propose to enroll 105 participants and allow for a dropout rate of 10% for an effective sample size of 100.

Inclusion criteria

1. Volunteer to participate in the study with informed consent;
2. Females aged 20-80 who are confirmed with cervical cancer and are treated with open radical hysterectomy and pelvic lymphadenectomy.

Exclusion criteria

1. Pregnancy, lactation, postmenopause, or planned pregnancy within two years;
2. Suspected or identified as other tumors of genital tract;
3. History of hyperparathyroidism, infectious diseases (tuberculosis, AIDS), autoimmune diseases, or digestive system diseases (malabsorption, crohn disease and dysentery);
4. Other diseases or heavy injuries that will interfere with the results;
5. Simultaneous participation in another clinical study with investigational medicinal product(s) or researcher thinks the subjects are not suitable for this trial

Outcomes measures

The primary outcome is the specific volume of hidden blood loss in patients after the operation.

The secondary outcomes are risk factors of hidden blood loss according to the results of multiple linear regression analysis.

Withdrawal Subjects must be withdrawn from the study when one of the following criteria occurs:

1. At their own request. At any time during the study and without giving reasons, a subject may decline to participate further. The subject will not suffer any disadvantages as a result;
2. In the investigator's opinion, continuation of the study treatment would be harmful to the subject's health;
3. Obvious non-compliance;
4. Lost to follow-up;
5. Pregnancy;
6. Other medical or surgical treatments of cervical cancer.

Safety assessments Safety will be assessed by renal and liver function test, electrolyte, routine blood test. Other indicators are detected during the operation and rehabilitation period. The occurrence of any adverse events in participants will be recorded in the case report forms during each patient visit. We will withdraw patients who have severe adverse events, as it is unsafe for them to continue the trial. Meanwhile, we will give them relevant medical care and follow them up until the reaction has terminated.

Statistic analysis

The gender, weight and height were used to calculate the patients' blood volume (PBV) according to the method of Nadler:

$PBV(L)=k1*height(m)^3+k2*weight(kg)+k3$

For female:k1=0.3561 k2=0.03308 k3=0.1833

And it has been confirmed that the total blood loss(TBL) in the perioperative period can be reflected through the reduction of Hct using the Gross's formula as follows:

$TBL(L)=PBV(L) * (Hctpre-Hctpost)/Hctave$

where Hctpre refers to the initial pre-opearative Hct, Hctpost is the Hct on the second or the third day post-operatively. And the Hctave is the average of Hctpre and Hctpost.

Finally, by subtracting visible blood loss (VBL) from TBL, we can get the HBL. For patiens who received transfusion or reinfusion during the operation, the formula changes into

HBL(L)=PBV(L)+blood infuses(L)-VBL(L).

Multiple linear regression analysis was applied to evaluate the risk of HBL related to fourteen independent variables including four qualitative variables(hypertension, diabetes, diagnosis according to the FIGO staging system and the pathological tumor type) and eight quantitative variables(age, BMI, the number of lymph nodes, the interval between biopsy and operation, surgical time, surgical bleeding, postoperative anticoagulant time, preoperative value of Hb, preoperative value of RBC and preoperative value of Hct). All statistical analyses were performed by SPSS 17.0 software package and the level of statistical significance was set at $P<0.05$. All independent variables were incorporated into the model using the method of “Enter”. Data are presented as mean ± standard deviation.