

VIETNAMESE MINISTRY OF HEALTH

REPORT RESULTS OF THE RESEARCH MANAGED BY MINISTRY OF HEALTH

**STUDY EXPANDED EFFICIENCY CONTRACEPTIVE AND
SAFETY OF TCU 380A IUD - SMB INDIAN COMPANY**

PRINCIPAL RESEARCHER: A. PROF. NGUYEN VIET TIEN MD, PhD.

Management's office : The National Hospital of Obstetrics and Gynecology

HA NOI, 2010

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Management's office : The National Hospital of Obstetrics and Gynecology

Management: Ministry of health

Duration: from 2006 to 2010

Total budget : VND 283, 200, 000

HA NOI, 2010

Số: BỘ Y TẾ
1011 /GM-BYT

CỘNG HOÀ XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập – Tự do – Hạnh phúc

Hà Nội, ngày 16 tháng 12 năm 2010

GIẤY MỜI

Kính gửi:

Bộ Y tế tổ chức phiên họp Hội đồng KHCN cấp Bộ (được thành lập tại Quyết định số 4929 /QĐ-BYT ngày 16/ 12 /2010 của Bộ trưởng Bộ Y tế) tiến hành nghiệm thu đề tài nghiên cứu khoa học công nghệ cấp Bộ:

Tên đề tài: Nghiên cứu mở rộng theo dõi hiệu quả tránh thai và độ an toàn của dụng cụ tử cung TCu 380A của công ty SBM- Ấn độ.

Chủ nhiệm đề tài: PGS.TS Nguyễn Viết Tiến- Thứ trưởng Bộ Y tế.

Đơn vị chủ trì đề tài: Bệnh viện Phụ sản Trung ương

Thời gian: 14g, ngày 22 tháng 12 năm 2010

Địa điểm: Phòng họp Vụ Khoa học và Đào tạo – Bộ Y tế

P411 Nhà Điều hành – Bộ Y tế – Số 138A Giảng Võ, Hà Nội

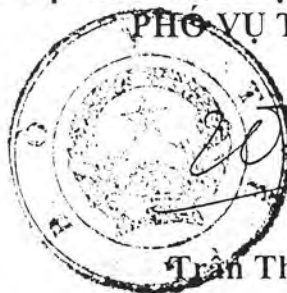
, Kính mời các thành viên Hội đồng và các quý vị đại biểu tới tham dự phiên họp đầy đủ và đúng giờ.

Xin trân trọng cảm ơn./.

Nơi nhận:

- Như trên;
- TT Nguyễn Viết Tiến (để báo cáo);
- Lưu: VT; K2ĐT(2);

TL. BỘ TRƯỞNG
KT. VỤ TRƯỞNG VỤ KHOA HỌC VÀ ĐÀO TẠO
PHÓ VỤ TRƯỞNG



Trần Thị Oanh

BỘ Y TẾ
Số: 4929/QĐ - BYT

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM

Độc lập – Tự do – Hạnh phúc

Hà Nội, ngày 16 tháng 12 năm 2010

QUYẾT ĐỊNH

Về việc thành lập Hội đồng Khoa học công nghệ
nghiệm thu đề tài khoa học công nghệ cấp Bộ

BỘ TRƯỞNG BỘ Y TẾ

Căn cứ Nghị định số 188/2007/NĐ-CP ngày 27/12/2007 của Chính phủ quy định về chức năng, nhiệm vụ, quyền hạn và cơ cấu tổ chức của Bộ Y tế;

Căn cứ Thông tư số 37/2010/TT-BYT ngày 16/8/2010 Quy định về quản lý đề tài nghiên cứu khoa học và dự án sản xuất thử nghiệm cấp Bộ Y tế;

Căn cứ Quyết định số 4391/QĐ-BYT ngày 08/11/2007 của Bộ trưởng Bộ Y tế về việc phê duyệt đề tài nghiên cứu khoa học cấp Bộ;

Xét biên bản họp Hội đồng khoa học cấp cơ sở của Bệnh viện Phụ sản Trung ương;

Xét đề nghị của Ông Vụ trưởng Vụ Khoa học và Đào tạo Bộ Y tế,

QUYẾT ĐỊNH:

Điều 1. Thành lập Hội đồng KHCN cấp bộ nghiệm thu chính thức kết quả nghiên cứu đề tài khoa học cấp Bộ:

Tên đề tài: Nghiên cứu mở rộng theo dõi hiệu quả tránh thai và độ an toàn của dụng cụ tử cung TCu 380A của công ty SMB- Ấn độ.

Chủ nhiệm đề tài: PGS.TS Nguyễn Viết Tiến.

Đơn vị chủ trì đề tài: Bệnh viện Phụ sản Trung ương.

Hội đồng gồm các nhà khoa học có tên trong danh sách kèm theo.

Điều 2. Hội đồng Khoa học công nghệ có nhiệm vụ đánh giá kết quả nghiên cứu của đề tài trên theo quy định đánh giá nghiệm thu các đề tài khoa học công nghệ do Bộ Khoa học Công nghệ và Bộ Y tế ban hành.

Điều 3. Quyết định này có hiệu lực kể từ ngày ký. Hội đồng sẽ giải thể sau khi hoàn thành các nhiệm vụ.

Điều 4. Các Ông Vụ trưởng Vụ Khoa học Đào tạo, Thủ trưởng đơn vị chủ trì đề tài và các Ông/Bà có tên trong điều 1 chịu trách nhiệm thi hành quyết định này./.

Nơi nhận:

- Như Điều 1 và 4;
- Bộ trưởng (để báo cáo);
- Lưu: VT; K2ĐT (2);

**KT. BỘ TRƯỞNG
THỨ TRƯỞNG**

Nguyễn Thị Kim Tiến

BỘ Y TẾ

CỘNG HOÀ XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập – Tự do – Hạnh phúc

DANH SÁCH

Thành viên Hội đồng KHCN nghiệm thu đề tài KHCN cấp Bộ

Tên đề tài: Nghiên cứu mở rộng theo dõi hiệu quả tránh thai và độ an toàn của dụng cụ tử cung TCu 380A của công ty SMB- Ấn độ.

(Kèm theo QĐ số /QĐ-BYT ngày tháng năm 2010 của Bộ trưởng Bộ Y tế)

	Họ và tên	Đơn vị	Chức trách trong Hội đồng
1.	PGS.TS Nguyễn Đức Hình	Trường Đại học Y Hà Nội	Chủ tịch Hội đồng
2.	GS. TS Trần Thị Phương Mai	Vụ sức khỏe bà mẹ và trẻ em Bộ Y tế	- Ủy viên Nhận xét
3.	PGS.TS Nguyễn Ngọc Minh	Trường Đại học Y Hà Nội	- Ủy viên Nhận xét
4.	PGS.TS Phạm Bá Nha	Bệnh viện Bạch Mai	- Ủy viên
5.	TS. Lê Hoàng	Bệnh viện Phụ sản Trung ương	- Ủy viên
6.	ThS. Nguyễn Minh Tuấn	Vụ Trang thiết bị và công trình y tế- Bộ Y tế	- Ủy viên
7.	TS. Trần Thị Oanh	Vụ Khoa học và Đào tạo	- Ủy viên

Thư ký khoa học: ThS. Đào Thị Hồng Hà

ThS. Lê Hiếu- Chuyên viên Vụ Khoa học và Đào tạo, Bộ Y tế.

MINISTRY OF HEALTH

Ref: 1011/GM-BYT

SOCIALIST REPUBLIC OF VIET NAM

Independence – Freedom – Happiness

Ha Noi, December 16th 2010

INVITATION

To :
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Ministry of health organizes Scientific committee meeting (pursuant to the Government's decision No.4929/QD-BYT of December 16th 2010 of Minister of Health) proceed with approve scientific and technologic research.

Title: Study expanded efficiency contraceptive and safety of Tcu 380A- IUD SMB, Indian company.

Principal researcher: **NGUYEN VIET TIEN MD., PhD. - Vice Minister of Health**

Management's office : The National Hospital of Obstetrics and Gynecology

Time: 2 PM, December 22nd 2010

Location: Scientific and Training Department - Ministry of Health

Room 411 Main buiding- Ministry of Health- 138A Giang Vo, Ha Noi.

We're inviting all of members in the Scientific Committee and Delegates respectfully coming to session completely and on time.

Yours sincerely,

Places received

- As above
- Nguyen Viet Tien-Deputy MOH
- Save: VT; K2DT(2)

Minister of Health

On behalf of Chief Scientific and Training Department

Deputy Chief

(Signed and sealed)

Tran Thi Oanh

MINISTRY OF HEALTH

Ref: 1011/QĐ-BYT

SOCIALIST REPUBLIC OF VIET NAM

Independence – Freedom – Happiness

Ha Noi, December 16th 2010

**DECISION OF ESTABLISH THE SCIENTIFIC COMMITTEE APPROVING
THE RESEARCH MANAGED BY MINISTRY OF HEALTH**

MINISTER OF HEALTH

- Pursuant to the Government's Decree No.188/2007/ND/CP of December 27th, 2007 defining the functions, tasks, powers and organizational structures of the Ministry of Health;
- Pursuant to the Government's circular No.37/2010/TT/BYT of August 16th, 2010 defining the scientific research and trial production project of the Ministry of Health;
- Pursuant to the Government's decision No.4391/QĐ-BYT of November 8th, 2007 regarding to approve scientific research managed by Ministry of Health;
- According to the meeting report of Scientific Committee of the National Hospital of Obstetrics and Gynecology;
- According to the proposal of Chief of Scientific and Training Department - Ministry of Health

DECIDES

Article 1. To Establish the Scientific Committee of Ministry of Health approving the results of the research officially.

Title: Study expanded efficiency contraceptive and safety of Tcu 380A- IUD SMB, Indian company.

Principal researcher: *NGUYEN VIET TIEN MD., PhD. - Vice Minister of Health*

Management's office : The National Hospital of Obstetrics and Gynecology

Committee include scientists whose name in list enclose.

Article 2. The Scientific Committee evaluated the result of the research following all rules for evaluation of scientific researches which promulgated by Ministry of Scientific and Ministry of Health.

Article 3. This Decision takes effect since the issued day. The Committee will be itself dissolved after finishing the tasks.

Article 4. Mr. Chief of Scientific and Training Department, the Chief managed the research and Mr./Mrs. with the name in Article 1 shall have to implement this Decision.

On behalf of Minister of Health

Vice Minister of Health

(Signed and sealed)

Nguyen Thi Kim Tien

The List numbers of Scientific Committee approving the study managed by MOH

No	Full name	Office	Position
1	A. Prof. Nguyen Duc Hinh, PhD.	Hanoi Medical University	Chairman
2	Prof. Tran Thi Phuong Mai, PhD.	The Reproductive Dept.-MOH	Reviewer
3	A. Prof. Nguyen Ngoc Minh, PhD	Hanoi Medical University	Reviewer
4	Pham Ba Nha, MD., PhD	Bach Mai Hospital	Member
5	Le Hoang, MD., PhD	NHOG	Member
6	Nguyen Minh Tuan,	MOH	Member
7	Tran Thi Oanh, MD., PhD	MOH	Member

The Secreteriat Boords: Dao Thi Hong Ha MD. MSc.; Le Hieu MSC.

Ha Noi, December 22th 2010

REPORT

THE SCIENTIFIC COMMITTEE APPROVED OFFICIALLY THE RESULT OF THE RESEARCH MANAGED BY MINISTRY OF HEALTH

The Scientific Committee of MOH had established, which pursuant to the Government's Decision No. 4929/QĐ-BYT of December 16th 2010 of Minister of Health proceed with official approval, and evaluated the results of the research managed by MOH.

A. General information:

Time: 2PM, December 22nd 2010

Location: Scientific and Training Department's boardroom

Title: Study expanded efficiency contraceptive and safety of Tcu 380A- IUD SMB, Indian company.

Principal researcher: *NGUYEN VIET TIEN MD., PhD. - Vice Minister of Health*

Management's office : The National Hospital of Obstetrics and Gynecology

Participants in the meeting:

Chairman: A. Prof. Nguyen Duc Hinh, PhD. – Hanoi Medical University

The member of committee 07 persons;
include:

Participants: 06 persons;

Absentee: 01 person (Nguyen Minh Tuan, MsC)

Secretary: Dao Thi Hong Ha MsC, Le Hieu MsC.

- From implement research: A. Prof. Nguyen Viet Tien MD., PhD. - Principal researcher, the members of group's study.

- Guest Leader, Department of Scientific Research of NHOG.

B. Content

1. Promulgating establish the Scientific Committee of Ministry of Health approving the results of the research.
2. Chairman: Nguyen Duc Hinh handles meeting
 - 2.1. Presentation by researcher Nguyen Thi Hong Minh, MD. Specific level 2- Director of the Center Reproductive Health Counseling and Family Planning-NHOG (representative of Research team): presented summary the result implement of research (enclose report of result of research).
 - 2.2. The main reviewers were reading comments, evaluations of the research (enclose commendation report of two reviewers: Prof. Tran Thi Phuong Mai, PhD.; A. Prof. Nguyen Ngoc Minh, PhD.).
 - 2.3. Members of the Committee discussed and exchanged views on implements, development and result of research (enclose opinion of detail report of Committee).
 - 2.4. The opinions of the owners and representatives of NHOG: Dr. Nguyen Viet Tien speaked for recieving the comments of the Committee: After hearing the comments of the reviewers of the Committee, head of the research answered questions from Committee and absorbed the opinions of the committee for completing the report.
 - 2.5. After discussing and hearing the responses of the researchers, the Committee voted to conduct evaluation of the results (enclose with the minutes of counting of votes):
 - a. Average criterion point 1, 2, 3: 54,3 points
 - b. Average criterion point 7: 0,25 points
 - c. Average total point: 92,2 points

Result of voting: research was evaluated with excellence (according to the Scientific Grade of the National Standards applying now).

Conclusion of Committee:

The Scientific Committee evaluated, approved the result of research with excellent.
Committee closed at 4 PM.

Secretary
(Signed)

Chairman committee
(Signed)

The comments of members of the Scientific Committee

(The Scientific Committee of MOH had established pursuant to the Government's Decision No. 4929/QĐ-BYT of December 16th 2010 of Minister of Health)

1. Prof. Tran Thi Phuong Mai (the main reviewer):

- The evaluation of the effectiveness, safety, acceptance of women for contraception is higher than 90%, high safety, no side effects, the acceptance of the user high.
- This study was designed strictly logical, large sample size, ensure reliability.
- Research conducted in six provinces, large sample size, ensure high reliability of research results.
- Funding for implement the research was fewer, but the result was very reliable.
- The percentage of contraceptive, acceptance was high (97%), the rate of side effects was low.
- Discuss the results reflect the advantages of using a contraceptive.
- The study has evaluated the effectiveness of the instruments, the consents of women, complications. The research had practical value for the medical care.
- Timing for follow up tool less, should continue to monitor further three years to side effects, to assess the quality of IUD after 5 years of use.

2. Prof. Nguyen Ngoc Minh (the main reviewer):

- Research has practical value, more content research, a large study sample size.
- The result shows that IUDs were highly effective, no side effects, the rate of acceptance in women high.
- Research staffs have extensive experience in implement research.
- Research has practical value and highly scientific.

3. Pham Ba Nha MD., PhD.

- Research has trial, no control. The topic has been conducted many different stages. This study was implemented on 6 provinces, over 2000 cases.
- The result shows that the high contraceptive, low incidence rate and high rate of acceptance. Research confirms the quality of IUDs.

- The content is deployed properly follow up approved research proposal, having scientific value and high practical value.

4. Le Hoang MD., PhD.

- Results of the research has high practical value, staff has extensive experience and research on the implementation of the approved content.
- Some subjects inserted within the age of 20, should be discussing these results.

5. Tran Thi Oanh MD., PhD.

- Agree with the comments of the Committee. The research has valuable scientific and practical high. The report presented the correct form, and logic.
- Regarding the products of topics: the slow progress of the research was to explain, the publishing of articles on scientific journals.

6. A. Prof. Nguyen Duc Hinh, PhD

- The research has high practical values, the research results got a quality constraints of contraceptives to serve the population of Vietnam.
- Beside IUDs, There are many other methods, but cost of service is high.
- Recommend the management agencies of suppliers to continue for following up IUDs used in community.

Explanation of managed office:

- We had some difficult conditions during implement research as funding. So we reported about slow progress reported to MOH.
- Some of the younger subjects, but these subjects were still eligible to participate in the research according to WHO standards.

REPORT RESULTS OF THE RESEARCH MANAGED BY VIETNAM MINISTRY OF HEALTH

**Title: STUDY EXPANDED EFFICIENCY CONTRACEPTIVE AND SAFETY OF TCU
380A IUD - SMB INDIAN COMPANY**

PRINCIPAL RESEARCHER: A.PROF. NGUYEN VIET TIEN MD, PhD.

Management's office : The National Hospital of Obstetrics and Gynecology

Management: Ministry of health

Secretary: Bạch Huy Anh MD, Msc.

Duration: from 2006 to 2010

LIST OF THE MAIN PARTICIPANTS

<i>No</i>	<i>Full name</i>	<i>Position</i>	<i>Department</i>
1	A. Prof. Nguyen Viet Tien MD, PhD	Director	ART centre
2	Dang Thi Minh Nguyet MD, PhD	Deputy	SI
3	Nguyen Thi Hong Minh MD., MD. Specialist level 2	Director	Family planning Centre
4	Nguyen Thi Ngoc Thuy MD., MD. Specialist level 2	Deputy	PII
5	Prof. Nguyen Duc Vy MD, PhD	Counsellor	NHOG
6	A. Prof. Ngo Van Toan MD, PhD	Counsellor	Medical University
7	A. Prof. Nguyễn Minh sơn	Counsellor	Medical University

	MD., PhD.		
8	Nong Minh Hoang MD. MSc.	Staff	Scientific Department
9	Bach Huy Anh MD, Msc.	Cheef secretary	Secretariat
10	Nguyen Huy Hung MD., MD. Specialist level 2	Deputy	Technical guideline
11	Ngo Toan Anh, bachelor	Staff	Diagnosis Centre
14	Tran Thi Thanh MD., MD. Specialist level 2	Staff	Technical guideline
15	Trinh Thi Thuy Hang, bachelor	Staff	Technical guideline
16	Lai Thi Thanh Mai, bachelor	Staff	Technical guideline

*The Mother and Child Health Protection/Family Planning Center (now the regional Reproductive Health Care Center) in provinces : Thai Binh , Nam Dinh, Ha Nam, Thai Nguyen, Thanh Hoa, Ha Tinh.

DIRECTOR

Signed & sealed

NGUYỄN VIỆT TIẾN

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SECTION A

SUMMARY OF MAIN FINDINGS

1. Main findings

1.1. *New findings:*

This is a clinical trial research (with follow-up) conducted along a time sequence from IUD insertion and during use traced, all complied with professional guidelines. The study assessed the efficiency of contraceptive, failure rate, withdrawn rate, safety rate and side effects of TCU 380A providing of the SMB India Company. Findings of the study will provide a scientific basis for managers to select another contraceptive method to provide customers for family planning purposes and to give customers more opportunities to choose the most suitable contraceptive method themselves for contraceptive.

The study also has been combined clinical examinations with tests during observation of the subjects. Cases of gynecological inflammation were all tested by microscope vaginal fluid or Sniff test and treated actively belong the causes until covered.

1.2. *Detailed findings*

A. Result of phase I

The study was conducted 465 women using Tcu 380A IUD in four districts belonging to provinces: Ha Nam, Nam Dinh, Thai Binh. Here are the main findings after 12 months:

1.2.1. The efficiency of contraceptive and the rate withdrawn of using TCu 380A-SMB IUD.

- After using IUD 12 monthes, there were any pregnant women found. The effectiveness of contraception after 12 months of using TCu 380A-SMB IUD was 100 %.

- The rate of women withdrawn to use TCU 380A –SMB IUD was 3.44%. Among them, withdrawn due to menorrhagia was 1.94%, due to abdominal pain and backache when menstruating was 0.64% and due to other reasons (desire more children, fatigue, etc.) was 0,86%.

1.2.2. The safety rate of subjects using TCu 380A-SMB IUD.

After using TCU 380A IUD-SMB for 12 months, there were any cases of IUD insertion affecting health. The total rate of women with menorrhagia after 12 months was 3.34%. The rate of women withdrawn as menorrhagia was 1.94%. The rate of women who had hypogastric abdominal pain and backache was 0.67%.

The rate of vaginitis after 12 months of using TCu 380A-SMB IUD was 3.79%. These cases were treated and then continued to use IUD. No woman withdrawn as vaginitis caused by TCu 380A-SMB IUD. Common causes of vaginal inflammation were bacteria, candidas and trichomonas. The rate of vaginal inflammation as bacteria was 2%, candidas was 0.22%, trichomonas was 0.67% and other reasons were 0.89%.

After 12 months of observation, 96.66% women had normal menstruation cycles, no one using TCu 380A-SMB IUD suffered from appendages or pelvic inflammation, as well as IUD into abdomen or ectopic pregnancy.

Ultrasonic scanning of all TCu 380A-SMB IUD using showed an image of the IUD positioned correctly in the uterus.

Results of this research showed a contraceptive effectiveness and safe degree of TCu 380A-SMB IUD approximately equal to the results of Nguyen Van Tuong's research on Indian TCu 380A-FaI IUD, the USA's Tcu 380A-FEI, Tcu 380A-Canada and Duong Thi Cuong's research on Tcu 380A-Netherlands in Vietnam. Those are the Tcu 380A IUDs currently and widely used in Vietnam's Family Planning program and accepted by Vietnamese women as a contraceptive method over the many past years.

B. Results of phase II (expansion phase)

The study has been continued to insert new Tcu 380A IUD on 1370 women in phase II (expansion phase) in six provinces of Vietnam: Ha Nam, Nam Dinh, Thai Binh, Thanh Hoa, Ha Tinh and Thai Nguyen. Here are the main findings after 12 months:

1.2.1. The efficiency of contraceptive and the rate withdrawn of using TCu 380A-SMB IUD.

- After using IUD 12 months, there were any pregnant women found. The effectiveness of contraception after 12 months of using TCu 380A-SMB IUD was 99.99 % (there were 2 cases gotten pregnancy in while of using IUD).
- The rate of women withdrawn using TCU 380A –SMB IUD: after 6 months was 1.7%, after 12 months was 2.6%. Among them, withdrawn as menorrhagia was 0.7% and 1.0%; as vaginitis was 0.2% and 0.5%; as IUD dropped was 0.4% and 0.4%, as abdominal pain and backache when menstruating was 0.3% and 0.3% and as other reasons (desire more children, fatigue, etc.) was 0,2 %.

1.2.2. Safety rate of subjects using TCu 380A-SMB IUD.

After using TCU 380A IUD-SMB for 12 months, there were any cases of IUD insertion affecting health. The total rate of women with menorrhagia after 12 months was 1.8%.

The rate of women vaginitis after 12 months of using TCu 380A-SMB IUD was 6.8%. These cases were treated and then continued to use IUD. No woman dropped out for vaginitis caused by TCu 380A-SMB IUD. Common causes of vaginal inflammation were bacteria, candidas and trichomonas.

After 12 months of observation, 90.6% women have normal menstrual cycles; 0.6% and 0.1% of subjects using TCu 380A-SMB IUD suffered from appendages or pelvic inflammation; there were no cases using IUD into abdomen or ectopic pregnancy. Especially, there were two cases gotten pregnancy when using IUD.

Ultrasonic scanning of all TCu 380A-SMB IUD using showed that 98.7% subjects using IUD positioned correctly in the uterus.

Results of this research also showed a contraceptive effectiveness (99.99%) and safety degree of TCu 380A-SMB IUD approximately equal to the results of Nguyen Van Tuong's research on India's TCu 380A-FaI IUD, the USA's Tcu 380A-FEI, Tcu 380A-Canada and Duong Thi Cuong's research on Tcu 380A-Netherlands in Vietnam. Those are the Tcu 380A IUDs currently and widely used in Vietnam's Family Planning program and accepted by Vietnamese women as a contraceptive method over the many past years.

1.2.3. Training benefits:

- The professional skills have been improved training in TCU 380A placing techniques and clinical research abilities of health staffs in the research team of the Mother and Child Health Protection/Family Planning Centers (now the regional Reproductive Health Care Centers) in the provinces (Ha Nam, Nam Dinh, Thai Binh, Thai Nguyen, Thanh Hoa and Ha Tinh).
- Report of the study is also a academic documents of science for reference for post-university students.

1.2.4. Society benefit

- The study is a scientific evidence of the implementation of TCu 380A IUD insertion techniques, contributing to increasing the rate of using modern contraceptive methods, reducing population growth and helping married couples practice family planning.
- And at the same time, improve clients' trust on this IUD.

2. Applicability

- The results will help manager divisions and policy makers to consider importing and applying TCu 380A IUD, which is suitable for Vietnamese women, into the family planning programs in Vietnam.
- The results also enable reproductive health facilities to understand the efficiency, safety and acceptability of this instrument in order to contraceptive.

3. Study evaluation

3.1. Progress

The study's duration met the MoH approved timeline.

3.2. Study objectives met

The study's objectives were all covered as set in the approved proposal.

3.3. Products met

The study's products were also met as compared to the products set in the proposal. The research team performed new TCu 380A IUD insertion for 1370 women with family planning demand and completed a report on results after 12 months.

3.4. Budget expenditure

Total budget for the study was VND 283,200,000; but 30% remain fund are not released until now . All expenses were controlled to belong the proposal and the regulations of Financial-Accounting dept-NHOG.

4. Suggestions

- This is a clinical trial with follow-up, so there were many difficulties in the process. Because of limited funding, re-training in TCU 380A IUD insertion techniques and subject observation and management skills was only done for the research staffs. The other medical staffs not involved in the research team were not trained. Therefore, we recommend the Scientific and Training Department-Ministry of Health of Vietnam and India SMB company provide additional funding for more training staffs, observations and management of participants using the TCU-380A SMB IUD.
- From the experiences are that before IUD insertion we need to better organize the work of counseling about family planning to reduce cases of withdrawn due to unreasonable reasons.
- Contraceptive methods of the campaigns are very effective, we recommend the facilities of reproductive health services and the Committee of Population, Family and Children in provinces to maintain and regularly organize that campaigns. We also recommend that the Ministry of Health and The Committee of Population, Family and Children in Vietnam to provide funding for the provinces to organize the campaigns of reproductive health service for people.

B. DETAIL STUDY REPORT

Introduction

The intrauterine devices (IUD) is one of the highly effective modern contraceptive methods widely in use over the world and Viet Nam. As early as 1909, Dr. Richard Richter of Germany began experimenting and developing IUDs, which were made of silk and inserted into the uterus to prevent pregnancy. The first plastic IUDs appeared on the scene in the 1960s and at the same time, copper-containing devices were tested on rabbits. Afterwards, many cooperative researches on family planning continued to improve the IUDs to their current form today.

In 1986, the UN Summit in Geneva, Switzerland recommended about the effectiveness of copper IUDs widely used in family planning in many countries. Each year, dozens of millions of women used this contraceptive method.

In Viet Nam, IUDs were accepted and used in 1960 in family planning by Vietnamese women. The middle year surveys of the of Population Department proves the rate of using IUDs in 2001 was 55.7% and 2004 was 55,9% [17].

Nowadays, IUDs currently have two general types in Viet Nam: TCu 380A IUDs and Multiload Cu375 SL IUDs. According to the Vietnam Committee of Population, Family and Chidrent; each year UIDs are provided to users from 1.7-1.9 millions, among which 70% is Tcu 380A. Both types are provided by the Pregna company of India. After a while in use, researches have been proved a high efficiency in pregnancy prevention (97.4%), acceptance from Vietnamese women (71%) and safety in use of IUDs [18].

With the goals of diversificating contraceptive methods and avoid exclusiveness in providing and distributing IUDs and ensure convenience and quality in IUDs provision services for customers, and with agreement of the

Scientific Committee – Ministry of Health (MOH) as well as MOH leaders, The National Obstetric and Gynecology Hospital associated with SMB Indian company and Provincial Protected Health Mothers and Child Centre/PL (now is Provincial Reproductive Health Care Centre) of 06 provinces (Ha Nam, Thai Binh, Nam Dinh, Thai Nguyen, Thanh Hoa, Ha Tinh) have been carried out a clinical trial to confirm the effectiveness in preventing pregnancy and safety level of the Tcu 380A IUD provided by SMB Company of India with the following objectives:

***General objective:** To determine the effectiveness in preventing pregnancy and safety level of Tcu 380A IUDs from SMB Company of India.

***Specific objectives:**

1. To determine effectiveness in preventing pregnancy and failure rate of Tcu 380A IUDs provided by SMB company for married women in reproductive age practicing family planning.
2. To discover the side effects after Tcu 380A IUD insertion as well as withdrawn rate.
3. To evaluate the acceptability and safety of this IUD to users.

CHAPTER 1. BACKGROUND

1.1. Physiology of conception

1.1.1. Definitions

Fertilization is the unification of a male cell called sperm with a female cell called oocyte cell to form a new cell called zygote.

Conception is fertilization followed by the nesting of the zygote. After conception, it develops into fetus and subsections.

The condition for conception is that the egg and sperm meet. Afterwards the zygote must move to the uterus, upon when the uterus' mucosa should be fully developed and ready.

1.1.2. The movement of spermatozoa and oocyte

the spermatozoa travel through the cervix and body of the uterus and into the Fallopian tubes

1.1.3. Fertilization and development

1.2. Intrauterine Devices

1.2.1. Mechanism and function of IUDs

1.2.2. Development of IUD

According to A.Southam of Britain's study, centuries ago Arabic, Turkish and Egyptian people who used camels to transport their merchandises through deserts learned to put a pebble in the camel's uterus to prevent it from getting pregnant while transporting.

In 1909, Richard Richter, a German doctor, for the first time practiced inserting an IUD made of silk threads of 27mm in width into human's uterus to prevent pregnancy.

In 1929, Ernst Gräfenberg(Germany)'s study where he practiced IUD insertion on 453 subjects showed many infection complications in the uterus, and thus IUD was not yet in use.

Thanks to the advent of antibiotics, research on IUDs was resumed. In 1959, Oppenheimet(Israel)'s study used Gräfenberg's study's IUDs on 1500 cases and found few gynecologic inflammation complications. Ishihama(Japan)'s study, which concluded on 20,000 women inserted with Ota IUDs, showed a high prevention rate.

In 1960, the second generation of IUD, Margulies Spiral, made of plastic with no metal and barium sulfate, was introduced. Chile's Jaime Zipper studied it on rabbits and proved the role in pregnancy prevention of IUDs with copper and the gradual reduction of copper in copper-containing IUDs.

In 1962, according to Hall and Stone (USA), there was a relation between IUDs and inflammation of the uterus' inner layer, and they also proved that plastic IUDs did not cause as much disturbance to the cell structure of the inner layer as metallic IUDs. Since then the program of cooperative research of many nations and family planning was established. IUDs were continued to be improved and perfected. Many IUD types were mass produced and applied in contraception such as: Ota, Gräfenberg, Dana, Multiload, T-shaped.

In 1970, Jaime Zipper (Chile) introduced the third generation of IUDs which contained copper including Copper T, Copper 7, with a minimum copper area of 200mm^2 .

China has successfully mass produced Shanghai V IUDs. The America continent area made copper-containing IUDs such as Multiload, Multiload Cu375SL, TCu200, TCu220C, TCu380, TCu 380A, FFS Cu 380.

In December 1986, at the Geneva Summit in Switzerland, UN stated a recommendation of using IUDs because this method is safe and highly effective.

1.2.3. Using IUD situation in the world

Since 1965, there were approximately 6 million women who used IUDs and after 5 years (1970) the number women who used IUDs contraception increased to 12 million. Until 1983 there were over 50 million women who used IUDs [40].

In 1999, reports of Skegg DC (Germany) published a study from 47 countries using IUDs to control birth rate which showed high efficiency and safety level [37].

Currently, there are two types of IUD in the world: one type with endocrine medicine and the other with just copper coating. For the type with endocrine medicine, when used hormones will be released to help with contraception. The type without endocrine medicine but copper coating include: TCu200, TCu220, TCu380, TCu380A, Multiload Cu 375 SL. The copper released from these IUDs assists in preventing pregnancy when used.

One of the biggest worries when using IUDs is the risk of pelvic inflammation, particularly in the first 4 months of usage. Thus, if the IUD user did not suffer from previous gynecologic inflammation, the rate of pelvic inflammation during use will be greatly reduced. The relation between using IUD and ectopic pregnancy was shown in many studies, that the rate of people using copper-containing IUDs and having ectopic pregnancy was lowest (0.3%) compared to other IUDs.

The most common side effect is a higher blood amount when menstruating and menorrhagia in the first few months, and has caused inconvenience for users and may even affect health due to higher blood loss.

1.2.5. Using IUD situation in Viet Nam

Since 1960, IUD has been put into use and considered one of the highly modern and effective contraceptive method. The number of users increases and become a popular contraceptive method in Vietnam. According to the mid-term investigation of The Bureau of Annual Statistics, the rate of using IUD is higher than that of other contraceptive methods.

Table 1.1. The rate of contraceptive usage in 2001-2004 [19]

Contraceptive method	2001	2002	2003	2004
IUD (%)	55,7	56,2	57,0	55,9
Condom (%)	7,8	8,4	7,5	9,3
Oral contraceptive pill (%)	10,0	10,5	11,4	11,9

The most common IUD in use in Vietnam is TCU 380A and Multiload Cu375 SL. Among them, TCU 380A IUD claimed 70% and Multiload Cu375 SL IUD claimed 30% of total usage. Currently, each year Vietnam used about 1 to 1.5 million TCU 380A IUDs provided by India's Pregnant company. In 2001, The Population, Family and Children Committee allotted 1250000 TCU 380A IUD for family planning audience in need. Until 2005 the amount of TCU 380A IUD given to users were about 1.5 million units. TCU 380A IUD produced by India have been accepted by Vietnamese women as a contraceptive method [13].

1.3. TCU 380A IUD

1.3.1. Situation using TCU IUD

Since 1982, TCU 380A IUD has been researched by The Population Council and over 70 countries has already use this type of IUD in all continents such as America, Africa, Asia and Latin America. Some countries such as Canada, Indonesia, India, China, etc. are producing the IUD.

Type TCU 380A IUD is shaped like the letter T such as TCU 200 IUD, 36mm length and 32mm wide, with two copper tubes at the horizontal branches and a total copper area of 380mm^2 . TCU 380A IUD has more copper area than previous copper-containing IUDs and is effective for 5-8 years and maybe for 10 years [3][18].

Since 1989, Vietnam used TCU 200 and 220 IUDs, and then TCU 380 IUD. In 1993 TCU 380A IUD types produced by Canada were used in Vietnam. TCU 380A IUD produced by India has been used in the family planning program in Vietnam since 1997. Every year nearly two million Vietnamese women use them. Over time and through researches, it is shown that the type of IUD produced by India ensures safety, efficiency and is accepted by Vietnamese women[18].

The TCU 380A type IUD produced by SMB Company in India meets international standards and has a structure similar to TCU 380A type IUDs of other companies in India and other countries in the world. Every year millions of IUDs were provided for the UN Population Fund (UNFPA) to serve the population and family planning programs worldwide. They are quality tested in independent international standards laboratories and meet international rules [18] [40].

1.3.2. TCu 380A IUD prescription

- Ideal for women who have children, normal genital apparatus and want to avoid pregnancy.
- Uterus with mark of caesarean operation can still use an IUD [3].

1.3.3. TCU 380A IUD Contraindications

Absolute contraindications: pregnancy, genital tract infections, clotting disorders, cardiovascular disease, cancer in female genital organs.

Relative contraindications : abnormal uterine cavity (fibroids, malformations), using anti-blood clot medicine, previous infections of upper genital tract, previous ectopic pregnancy, haven't had any child. [3]

1.3.4. Timing of insertion, remove and replacement

Place and remove the TCU 380A IUD: IUD insertion at the completion of menstruation cycle is best because the cervix is open and more importantly there is no pregnancy. IUD should not be placed immediately after giving birth because the rate of IUD sliding down is high. IUD should be placed at least 8 weeks after giving birth; and can be placed after abortion.[2]
Replace the TCu 380A IUD: IUD can be left in the uterus for 5-10 years until replacement, if it is the hormone type (Progestatif) then it must be replaced after 5 years [2].

1.3.5. Complications and side effects of TCu 380A IUD

These side effects and complications can be encountered while using IUD:

- Sub-pelvic pain: commonly experienced as the uterus contracts when a strange object is present, treated by using painkillers in the first few months. Sometimes contraction of the uterus can expel the IUD.
- Menstrual pain: pain in the abdominal region when menstruating, switch to non-copper IUDs in these cases.
- Menstrual disorders: the most common side effect encountered when using IUD, it claims 10-15% of the cases of compulsory IUD removal in the first year of use.
- IUD slip: is seen in the first year of use. Factors affecting IUD slip: age, time of giving birth, type of IUD, inserter's experience, placement time.
- Uterus puncture: very rarely seen, about 1.2% of insertions, if detected right after insertion then IUD can be removed and the uterus can be saved.
- IUD into abdomen: can be right when inserting or gradually over time.

- Genital infection: a complication that may cause infertility, incidence rate is at 3-9%.
- Pregnancy with IUD: incidence rate is at 0.5-5%
- IUD and ectopic pregnancy: IUD prevents the zygote from nesting in the uterine cavity, but cannot prevent it from nesting outside the cavity. However until now no study has made sure that IUD causes ectopic pregnancy.

1.3.6. Return of fertility after IUD removal

When you want to get pregnant again, simply remove the IUD and the rate of re-fertility is as follows: 30% after 1 month of removal, 50% after 3 months of removal, 70% after 12 months of removal, and 90% after 24 months of removal. However about 10% of cases suffer from secondary infertility due to cervical infection.

1.3.7 Effectiveness of TCu 380A IUD in preventing pregnancy

For non-active ingredient (copper, hormones) IUDs, pregnancy prevention is at 95-96%. But for the TCu 380A IUD, the rate is at 99%. IUD is currently the most widespread contraceptive method in our nation. Its high rate of pregnancy prevention has contributed to reducing birth rate and bringing economical profit to our nation's development.

CHAPTER 2. METHODOLOGY

2.1. Subjects

Women in reproductive age who are married, have had at least one child, want to practice family planning, are willing to use IUDs and do not have any contraindications with TCu 380A-SMB IUD insertion; also are selected through the checklist (enclosed in the appendix).

2.1.1 *Selected criteria*

- Women in reproductive age (15-49, WHO standards), have had at least one child.
- Clients need of family planning and are willing to use TCU 380A IUD provided by SMB Company of India.
- Prescriptions of inserting TCU 380A IUD met.
- Have regular menstruation.
- Abilities to comply with conditions of the study.
- Suitable with standards of the checklist of history, history of Obstetrics & Gynecology and General body as well as obstetrical examinations.
- Is not using any IUDs now.

2.1.2. *Excluded criteria*

- Unmarried women, married but childless and outside the reproductive age
- Irregular menstruation
- Do not meet checklist qualifications
- Unwilling to use TCU 380A IUD
- Contraindicated for TCU 380A IUD insertion
- Is using another contraceptive method.

2.2. *Sites and time of the study*

Phase I (is requested by MOH):

- Beginning selection of subjects in February 2005 and implementation of insertion and research from April 2005 to March 2007.
- Research sites in four districts of three provinces:
 - + Ly Nhan district of Ha Nam province.
 - + My Loc and Nghia Hung district of Nam Dinh province.
 - + Tien Hai district of Thai Binh province.

Phase II:

- Beginning selection of subjects in June 2007 and implementation of insertion and research to December 2008. And continuously following up to 2010.
- Study sites in six provinces:
 - + Ha Nam province.
 - + Nam Dinh province.
 - + Thai Binh province.
 - + Thai Nguyen Province
 - + Thanh Hoa Province
 - + Ha Tinh Province

2.3. Study design

This is an opened clinical trial, along the track, including 2 phases and no control groups. The study is evaluated by the intervention assessment model of duration before and after the experiment. The reason there is no control group is that there were some other type of TCU 380A IUDs which have the same quality standards that are internationally accepted and are being widely used in family planning program in Vietnam for years (comparing with the results of previous studies in Vietnam).

Tool:

- + Personal medical records, unified questionnaires to observe and interview

IUDs' users as health workers visit them and record down. After IUDs insertion, periodically in the final month of the season, subjects were at the clinic appointment to the medical sites. The information collected through questions and diagnosis profiles will be recorded to track objects and medical examination.

2.4. Sample size and Sampling

Sample size is determined by the following formula

$$n = \frac{\left(z_{(1-\alpha/2)} \sqrt{p_0(1-p_0)} + z_{(1-\beta)} \sqrt{p_a(1-p_a)} \right)^2}{(p_0 - p_a)^2}$$

Note: formula of S.K.Lwanga & Lemeshow Sample size determination in health studies WHO 1991, page 29.

Of which:

n = minimum sample size

p_0 = the rate of contraceptive success of previous studies was 85%

p_a = the rate of contraceptive desired of this study was 90%

$\alpha = 0,05$, $Z_{2(1-\alpha/2)}$: Score reliability at 95% probability (= 1.96)

Significance = 0.5, power model = 90%; $\beta = 0,1$; the value of $Z(1 - \alpha)$: 1.282.

After calculations, the minimum number of subjects were 382 people. An addition of 20% subjects were picked to make up for subjects who may stop cooperation and discontinue in the process of research

Total sample size in phase 1: $n = 458$ women

Total sample size in phase 2: $n = 1370$ women

* Sampling

Select all the women who have had at least one child, in child-bearing age, have needs for family planning and volunteer to use TCU 380A IUDs provided by SMB Company, not contraindicated for TCU 380A IUD and meet set

standards of research's participants, the first phase from February to April on 2005-2007 in the district. The women who were selected must meet standards in the checklist. After sampling, the number of subjects in the research was 465 women. In phase II from June 2007 to December 2008-2010 IUDs was inserted for 1370 women.

Data collection and analysis:

- Use unified questionnaires to interview, observe and visit subjects in the time of research, every 3 months, six months, 12 months.
- Questionnaires will then be collected, coded, input and analyzed using EPI-INFO 6.04 Statistical software
- Test χ^2 (Chi-Square) is used to compare rates.

2.6. Study steps

2.6.1. Training health workers

- Training on gynecological diagnosis and using a checklist to select subject
 - + Technical Training in gynecology: gynecological techniques, how to identify normal gynecology through the naked eye, how to obtain vaginal fluid and test vaginal cells to assume vaginal cleanliness, fresh screening techniques, Sniff test techniques.
 - + Training on using a checklist to select a subject that meets all standards.
 - + Training on how to insert and remove a TCu 380A IUDs.
- Training on how to use the periodical subject observation questionnaires.

2.6.2. TCu IUDs insertion and necessary medicine provision

Practice TCu 380A IUDs insertion to the professional guidelines. The timing of insertion is right after menstruation and no prior intercourse.

Necessary medicine for TCu 380A IUDs users are: antibiotics such as Amoxicillin 500mg x 2 pills/day x 5 days, or Doxylin 100mg x 2 pills/day x 5 days, contraction-reducing medicine Spasmaverin 40mg x 4 pills/day x 5 days, or light painkillers such as Paracetamol 500mg x 2 pills/day x 3 days for prescriptive subjects.

2.6.3 Organize periodical examinations

Interview and examination every 3 months, 6 months and 12 months: full-body and gynecologic diagnosis, test vaginal fluid for inflammation cases, locate the position of IUD via ultrasound in cases where IUD thread is not found in vagina, locate IUD position, genital inflammation, menstruation, lower abdominal pain, pregnancy, IUD slip, etc.

2.6.4 IUD users observation and management

Information gathered from subjects is recorded in notebooks and observation tickets:

- Subject's full name, age, occupation, residence.
- Disease history, gynecology and gynecology inflammation history.
- Vaginal fluid test results.
- General body and gynecological diagnosis.
- Menstruation: regular/irregular/menorrhagia/excessive/none
- Pregnant or not pregnant.
- Gynecological inflammation symptoms: leucorrhoea, hypo gastric pain, vaginal fluid test.
- Hypo gastric abdominal pain.
- IUD's position.
- Had ectopic pregnancy or not
- IUD slipped or not
- Acceptance to use, number of people discontinued, reasons to discontinue.

2.6.5. Report after 12 months of use

2.7. Statistics achieved

Content	Statistic	Collection method
General information	- Characteristics of subject: age, residence, occupation, number of children.	Observation ticket and interview
Content 1: determining pregnancy prevention effectiveness and failure rate when using TCu 380A-SMB IUD	- Rate of non-pregnancies while using IUD - Rate of pregnancy while using IUD	Subject interviews, periodic diagnosis and 3 months observation tickets, tests, ultrasound tests
Content 2: studying side effects and safety level of using TCu 380A-SMB IUD	- Rate of pelvic inflammation of users - Rate of vaginal inflammation - Rate of lower abdominal pain leading to compulsory IUD removal - Rate of menorrhagia/prolonged bleeding - Rate of regular menstruation - Rate of irregular menstruation - Rate of no menstruation when using IUD - Rate of ectopic pregnancy	Subject interviews, periodic diagnosis and 3 months observation tickets, tests, ultrasound tests
Content 3: evaluating acceptance and	- Rate of IUD slip - Rate of acceptance - Rate of withdrawn	Subject interviews, periodic diagnosis and 3 months

withdrawn rate of people using TCu 380A- SMB IUD.	- Reasons of withdrawn	observation tickets, ultrasound tests
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2.8. Standards of the Study

- User: those who are currently using IUDs.
- Discontinued: those who no longer continue to use IUDs regardless of reason.
- The effectiveness of prevention pregnancy: the rate between the number of non-pregnant IUDs users and the total number of IUDs users.

$$\text{Effectiveness} = \frac{\text{Number of non-pregnant IUDs users}}{\text{Total number of IUDs users}} \times 100$$

- Failure rate: the % aged rate between the number of pregnant IUD users and the total number of IUD users.

$$\text{Failure rate} = \frac{\text{Number of pregnant IUDs users}}{\text{Total number of IUDs users}} \times 100$$

- Withdrawn rate: the % aged rate between the number of discontinued IUDs users and the total number of continuing IUDs users.

$$\text{Withdrawn rate} = \frac{\text{Number of discontinued IUDs users}}{\text{Total number of continuing IUDs users}} \times 100$$

- Vaginitis are cases where vaginal cells were tested at degree III, IV or Sniff tested (+), or fresh screened and detected candidas, trichomonas or gonococcus, etc.

- Normal, regular menstruation: 28-30 days cycle, menstruating for 5-7 days, amount of blood 60ml - 80 ml/day.
- No menstruation: Menstruation is not seen for 3 months or longer.
- Menorrhagia: vaginal bleeding for over 7 days.
- Bleeding menstruation: amount of blood during menstruation exceeds 200ml/day.
- IUDs in place: in the uterine cavity.
- Irregular menstruation: changes around 28-35 days for a cycle.

2.9. Ethical clearance

Implementation of the topic has been approved by the Scientific Committee -Ministry of Health, Bureau of Science and Training-Ministry of Health, officials of the Ministry of Health, Central Gynecology Hospital, Mother and Child Health Protection and Family Planning Center (now Reproductive Health Care Center) and Branch Council of Gynecology and Planned Childbearing of 6 provinces: Ha Nam, Nam Dinh Thai Binh, Thai Nguyen, Ha Tinh, Thanh Hoa, the health centers in the districts with subjects, and especially by the research subjects themselves.

The topic is also to serve the work of population management and family planning, to help clients have more benefit and a chance to choose the most suitable contraceptive method in effectiveness and cost for them.

Results of the study will help to vary contraceptive methods and avoid exclusiveness in providing contraceptive methods, giving clients convenient and high quality contraceptive provision services, which will help increase the rate of contraceptives usage and reduce population growth.

All information in the study is guaranteed in secrecy and protected.

CHAPTER 3

RESULTS

A. Phase

I

After the Technical and Scientific Department - Ministry of Health through the research proposal on February 24th 2005, from February 26th 2005, the team's study has coordinated with health personnel selection of district and commune audience research. Associated with burning to make family planning campaign in the province, from April 22nd 2005 to April 28th 2005, the team's study along with health personnel district, inserted TCU 380A SMB IUD for 465 women in the four districts: Ly Nhan district in Ha Nam province; My Loc and Nghia Hung district in Nam Dinh, Tien Hai district in Thai Binh province.

Table 3.1. The number of subjects in the provinces

Serial number	Province	TCu 380A-SMB IUD	
		n	%
1	Ha Nam	155	33,33
2	Nam Dinh	160	34,41
3	Thai Binh	150	32,26
	<i>Total</i>	465	100

Subjects were the same in three province. Each province has 32.36% - 34.41 %.

3.1. Subjects characteristics

3.1.1. Age of Subjects

Table 3.2. Age of subjects in the group and area

Age group	Ha Nam		Nam Dinh		Thai Binh		Total		p
	n	%	n	%	n	%	n	%	
19	0		1	0,63	0		1	0,22	
20-24	37	23,87	28	17,50	19	12,67	84	18,06	>0,05
25-29	43	27,74	40	25,00	39	26,00	122	26,24	
30-34	37	23,87	37	23,12	35	23,33	109	23,44	
35-39	19	12,26	33	20,63	28	18,67	80	17,20	
40-44	14	9,03	21	13,12	25	16,67	60	12,90	
45-46	5	3,23	0		4	2,66	9	1,94	
<i>Total</i>	<i>155</i>	<i>100</i>	<i>160</i>	<i>100</i>	<i>150</i>	<i>100</i>	<i>465</i>	<i>100</i>	

Women who using TCU 380A IUD in the 25-29 age group accounted for 26.24 %. The rate of user in the 30-34 age group was 23.44 %. In 20-24 age group was 18.06 %, in 35-39 was 17.20 % and in 40-44 age was 12, 90 %. Other age groups have lower utilization rate. The difference in age groups using TCU 380A IUD-SMB statistically not significant with $P > 0.05$.

3.1.2. Occupation

Table 3.3. Occupation

<i>Occupation</i>	Ha Nam		Nam Dinh		Thai Binh		Total		P
	n	%	n	%	n	%	n	%	
Farmer	151	97,42	152	95,00	140	93,33	443	95,27	< 0,05
Government employee	4	2,58	3	1,88	8	5,33	15	3,23	
Free trade (Housewife, business, etc.)	0	0	5	3,12	2	1,34	7	1,50	
<i>Total</i>	<i>155</i>	<i>100</i>	<i>160</i>	<i>100</i>	<i>150</i>	<i>100</i>	<i>465</i>	<i>100</i>	

Farmers accounted for 95,27 %. Government employees were 3,23 % and free trade were 1.5 % . There has significant difference between the two groups in terms of occupation with $P < 0.05$.

3.1.3. Number of children

Table 3.4. Number of children

No. of children	Ha Nam		Nam Dinh		Thai Binh		Total	
	n	%	n	%	n	%	n	%
1 child	86	55,48	116	72,50	109	72,67	311	66,88
≥ 2 children	69	44,52	44	27,50	41	27,33	154	33,12
<i>Total</i>	<i>155</i>	<i>100</i>	<i>160</i>	<i>100</i>	<i>150</i>	<i>100</i>	<i>465</i>	<i>100</i>

The rate of women had one child accounted for 66.88 % and those who had more than two children was 33.12 %.

3.1.4. The result of gynecological examination for subjects before insertion IUD

Table 3.5. Gynecological examination results before insertion IUD

Symptom and test	Ha Nam (n=155)		Nam Dinh (n=160)		Thai Binh (n=150)		Total (n=465)	
	n	%	n	%	n	%	n	%
Bacterial vaginosis history, produced leucorrhoea	3	1,94	16	10,00	7	4,67	26	5,59
Regular menstrual history	155	100,0	160	100,0	150	100,0	465	100,0
Cervical , uterus, normal sub-division	155	100,0	160	100,0	150	100,0	465	100,0
Vaginosis	10	6,45	3	1,88	4	2,67	17	3,66
Fresh inspiration bacteria (+++), or test sniff dương tính	10	6,45	3	1,88	4	2,67	17	3,66

Women have regular menstrual, cervix, uterus and normal sub-division accounted for 100 %. The prevalence of women with a history of produced leucorrhoea and vaginitis was 5.59%. Women who vaginitis, were not inserted IUD accounted for 17 (3.66%). Slight vaginitis cases, fresh inspiration bacteria sniff test (+++) or (+). These cases have been treated from 1-2 phase oral antibiotics and vaginal, each course of treatment for 7 days and the gap between 1-2 weeks. Then, these women are pelvic exam and tests the bacteria from the vagina change in inflammation, group's study began to insert IUDs.

3.2. Effective contraception and the failure rate

After 3 months, 6 months and 12 months insertion IUD TCU 380A-SMB IUD can not find any case pregnancy during using. The effectiveness of TCU 380A-SMB IUD was 100%.

3.3. Side effects and safety of IUD

After 6 months, the rate of women have menorrhagia after using IUD TCU-380A SMB was 0.43%. After 12 months, this rate was 3.34%. Difference between women menorrhagia when using SMB-380A IUD TCU after 6 months and 12 months no statistically significant with $p > 0.05$.

After 6 months using TCU 380A IUD-SMB, the proportion of women have vaginitis was 2.61%. This rate after 12 months TCU 380A IUD insertion-SMB was 3.79%. Difference in the proportion of women have vaginitis after IUD insertion 6 months and 12 months no statistically significant with $p > 0.05$.

The rate of women have vaginitis caused by bacteria after 6 months using TCU 380A IUD-SMB was 1.74%. After 12 months of insertion was 2.0%.

The rate of women have vaginitis by candidas was 0.22% after 12 months.

The rate of women have vaginitis by trichomonas after 6 months using TCU 380A IUD-SMB was 0.43%. After 12 months was 0.67%.

Difference causes inflammation of the vagina after 6 months and after 12 months no statistically significant with $p > 0.05$.

After 6 months using TCU 380A IUD-SMB, the proportion of women hypogastric abdominal pain, backache when they have menstrual was 0.67% .

The difference in the rate of women who have hypogastric abdominal pain, backache when menstruating after 6 months and after 12 months of follow statistically insignificant with $p > 0.05$.

After 12 months, none of case ectopic pregnancy or the IUD into the abdominal cavity when using TCU 380A -SMB IUD.

After 12 months of use, none of case TCU 380A -SMB IUD in the wrong location such as IUD is upside down or no IUD in the uterus.

After 12 months using IUD insertion, the rate of women have regular menstrual was 87,97%. And the rate of women has irregular menstrual from 30-35 days was 8.69%. The rate of women have vaginitis was 3.79% and 100% of IUD in uterus. Research results showed that none of women used not IUD were assigned secondary infections, pelvic inflammation, ectopic pregnancy and intra-abdominal IUD.

After 6 months, the proportion of women withdrawn continue to use the TCU 380A IUD-SMB was 1.08%. The rate of women withdrawn using TCU 380A IUD-SMB was 3.44% after 12 months. There was significant difference between in using TCU 380A IUD-SMB after 6 months and 12 months with $p < 0.02$

After 6 months of insertion, the proportion of women withdrawn using IUD TCU-380A SMB because of menorrhagia was 0.43%. The rate of women give up after 12 months using TCU 380A IUD-SMB was 1.94%.

The rate of women withdrawn use the SMB-380A IUD TCU because of have hypogastric abdominal pain, backache after menstruation after 6 months was 0.43%. After 12 months of use was 0.64%.

The rate of women withdrawn to use the SMB-380A IUD TCU by other reasons (Desire formore children, etc.) after 6 months was 0.22%. After 12 months was 0.86%.

No statistical difference between two groups withdrawn after 6 months and after 12 months with $p > 0.05$.

After 6 months, the rate of adoption TCU 380A IUD was 98.92%-. After 12 months, was 96.56%-SMB. The difference in adoption rate of using TCU 380A IUD-SMB after 6 months and 12 months no statistically significant $p > 0.05$.

TCU-380A IUD insertion after SMB 12 months, the proportion of women having regular menstrual were currently 87.97%. the rate of women have menstrual irregularities was 8.69% and the proportion of women have menorrhagia was 3.34%.

Before IUD insertion TCU-380A IUD , the proportion of womenvaginitis was 3.66%. This rate was 3.79% after 12 months IUD insertion. The difference is not statistically with $p > 0.05$.

Results of phase I has been review and acceptance by The Technical Scientific Department - Ministry of Health on May 16th 2006 , becoming the basis for the Ministry of Health consideration and direct the deployment of further research in phase II.

B. Phase II expansion

Table 3.6. The number of subjects in the provinces

Serial number	Provinces	TCu 380A-SMB IUD	
		n	%
1	Thai Nguyen	253	18,5
2	Ha Nam	249	18,2
3	Nam Dinh	251	18,3
4	Thai Binh	258	18,8
5	Thanh Hoa	221	16,1
6	Ha Tinh	138	10,1
	<i>Total</i>	1370	100,0

Subjects were the same in three province. Each province has from 10,1% to 18,8%.

3.1. Subjects characteristics

3.1.1. Age of Subjects

Table 3.7. Age of subjects in the group and area

Age group	Quantity	%
<20	12	0,9
20-24	261	19,1
25-29	361	26,4
30-34	356	26,0
35-39	278	20,3
40-44	72	5,3
45-49	30	2,2
Total	1370	100,0

Table 3.8. Age of subjects in the group and study area

Age	Province						Total
	Thai Nguyen	Ha Nam	Nam Dinh	Thai Binh	Thanh Hoa	Ha Tinh	
< 20	6	1	1	1	3	0	12
	50%	8.3%	8.3%	0.3%	25%	0%	100%
20-24	91	25	48	30	46	21	261
	34.9%	9.6%	18.4%	11.5%	17.6%	8%	100%
25-29	63	65	73	67	59	34	361
	17.5%	18%	20.2%	18.6%	16.3%	9.4%	100%
30-34	58	80	50	71	53	44	356
	16.3%	22.5%	14%	19.9%	14.9%	12.4%	100%

35-39	26	74	47	45	60	26	278
	9.4%	26.6%	16.9%	16.2%	21.6%	9.4%	100%
40-44	8	4	25	26	0	9	72
	11.1%	5.6%	34.7%	36.1%	0%	12.5%	100%
45-49	1	0	7	18	0	4	30
	3.3%	0%	23.3%	60.0%	0%	13.3%	100%
Total	253	249	251	258	221	138	1370
	18.5%	18.2%	18.3%	18.8%	16.1%	10.1%	100%

26.4% of women using TCU 380A IUD in the 25-29 age group. In the 30-34 age group was 26%, 20-24 was 19.1%, 35-39 was 20.3% and 40-44 was 5.3%. Other age groups have lower utilization rate. No significant difference among age group with $P>0.05$.

3.1.2. Occupation

Table 3.9. Occupation in study area

Occupation	Province						Total
	Thai Nguyen	Hà Nam	Nam Dinh	Thai Binh	Thanh Hoa	Ha Tinh	
Farmer	218	233	241	241	177	109	1219
	17.9%	19.1%	19.8%	19.8%	14.5%	8.9%	100%
Housewife	14	0	0	1	6	9	30
	46.7%	0%	0%	3.3%	20.0%	30.0%	100%

Government employee	8	13	5	10	7	18	61
	13.1%	21.3%	8.2%	16.4%	11.5%	29.5%	100%
Business	6	0	1	0	5	1	13
	46.2%	0.0%	7.7%	0.0%	38.5%	7.7%	100.0%
Worker	2	2	4	6	15	1	30
	6.7%	6.7%	13.3%	20.0%	50.0%	3.3%	100.0%
Free trade	1	0	0	0	3	0	4
	25.0%	0.0%	0.0%	0.0%	75.0%	0%	100.0%
Others	4	1	0	0	6	0	11
	36.4%	9.1%	0%	0%	54.5%	0%	100.0%
Total	253	249	251	258	221	138	1370
	18.5%	18.2%	18.3%	18.8%	16.1%	10.1%	100.0%

Farmers used TCu 380A-SMB IUD accounted for 89% . Government employees were 3,23 % and free trade were 4,5% and workers were 1,5%. There has significant difference among groups in terms of occupation with $P<0.05$.

3.1.3. Number of children

Table 3.10. Number of children

No. of children	Province						Total
	Thai Nguyen	Ha Nam	Nam Dinh	Thai Binh	Thanh Hoa	Ha Tinh	
1 child	125	27	50	34	79	32	347
	36.0%	7.8%	14.4%	9.8%	22.8%	9.2%	100.0%
≥2 children	128	222	201	224	142	106	1023
	12.5%	21.7%	19.6%	21.9%	13.9%	10.4%	100.0%
Total	253	249	251	258	221	138	1370
	18.5%	18.2	18.3%	18.8%	16.1%	10.1%	100.0%

Women who had one child accounted for around 25,3% and 74,7%.had more than two children.

3.3. Effective contraception and failure rate

Table 3.11. The effective birth control while using the IUD in the study phase

Pregnancy status	After 6 months insertion IUD	After 6 months insertion IUD
Pregnancy	2	2
Not pregnancy	1368	1333
Total	1370	1335

IUD insertion after 6 months and 12 months showed two cases pregnancy during use.

3.4. Measure the side effect and safety

3.3.1. Menstrual of user

Table 3.12. Menstrual change after 12 months of cumulative use

Menstrual	After 6 months N=1368		After 12 months N=1332	
	n	%	n	%
Regular menstrual period	1198	87.6	1206	90,6
Irregular menstrual period	136	9.9	98	7.2
Menorrhagia	33	2.4	24	1.8
No menstrual longer 3 months	1	0.1	4	0.4
Tổng	1368	100	1332	100

After 6 months, the rate of women have menorrhagia when using TCU 380A IUD was 2.4%. After 12 months, it was 1.8%. Difference in the proportion of women have menorrhagia when using SMB-380A IUD TCU after 6 months and 12 months no statistically significant with $p > 0.05$

3.3.2. Gynecological inflammation of users

Table 3.13. Gynecological acute situation when IUD use with time

Gynecological inflammation	After 6 months N=1368		After 12 months N=1332	
	n=	%	n=	%
No inflammation	1240	90.5	1225	92.1
Vaginitis	106	7.9	93	6.8
Inner epithelium of uterus	7	0.5	5	0.4
Appendage	10	0.7	8	0.6
Pelvic paint	5	0.4	1	0.1
Total	1368	100	1332	100

After 6 months using TCU 380A IUD-SMB, the proportion of women have vaginitis was 7.9%. This rate after 12 months TCU 380A IUD insertion-SMB was 6.8%. The difference in the proportion women have vaginitis after IUD insertion after 6 months and after 12 months no statistically significant with $p>0.05$.

3.3.3. Other side effect and hazard

After 6 months using TCU 380A IUD-SMB, there had one case of ectopic pregnancy, is not any IUD into the abdominal cavity. After 12 months had a case of IUD into abdomen.

3.3.4. The safety of IUDs

Table 3.14. The safety of IUD with time

Use IUD status	After 6 months		After 12 months	
	n	%	n	%
Continuous	1341	98.3	1333	97.4
Give up	27	1.7	35	2.6

After 6 months of use, the proportion of women withdrawn to use the TCU 380A IUD-SMB was 1.7%. %age of women withdrawn to use the TCU 380A IUD after 12 months-SMB was 2.6%. The difference give up using Tcu 380A SMB IUD after 6 months and after 12 months stastictics with $p<0.02$.

3.4.2. Causes of give up

Table 3.16. Causes of give up

Causes	After 6 months		After 12 months	
	n	%	n	%
Gynecological inflammination	3	0.2	7	0.5

Menorrhagia	10	0.7	14	1
Coil drip	6	0.4	6	0.4
Stomache	4	0.3	4	0.3
Not accept	2	0.1	2	0.1
Other reasons	2	0.1	2	0.1

After 6 months of insertion, the proportion of women using IUD TCU-380A SMB give up because of menorrhagia was 0.7%. %age of women give up after 12 months using TCU 380A IUD-SMB was 1.94%.

The rate of women withdrawn to use the SMB-380A IUD TCU by hypogastric abdominal pains, backache when having menstrual after 6 months of use was 0.3%. This rate after 12 months of use was still 0.3%. Tha rate of women withdrawn to use the SMB-380A IUD TCU by other reasons (Desire formore children, affect couper relationship, etc.). After 6 months of use was 0.1%. This rate after 12 months of use was also 0.1%. The difference in the cause withdrawn to use the SMB-380A IUD TCU no statistically significant $p > 0.05$.

CHAPTER 4. DISCUSION

4.1. Common feature subjects

Most women use the IUD TCU 380A-SMB in 25-29 age group accounted for 26.4%, followed by 30-34 age group account for 26%. The rate of women using IUD TCU 380A-SMB in 25-34 was 52.4%. In 25-34 age group, Vietnamese women typically from 1-2 children and has had enough children they wish, so their requirement was dilated gap of birth and stop to give birth. The rate of used TCU 380A SMBs IUD in the 25-34 age-group was also higher than other age group. This rate was similar studies of Nguyen Van Tuong about TCU Fai India IUD (48.52%) [18].

The majority (88.97%) women using the TCU-380A SMB IUD was farmer. This rate was higher than Nguyen Van Tuong research about TCU Fai India IUD (60.67%) [18]. May be due to the study area was rural and live mainly in agricultural production, so the number of women was more than other professions. The rate of government employee TCU-380A SMB IUD was not high (3.23%).

Researchers do not make IUD insertion for women without children, women should use SMB-380A IUD TCU all have at least one. The rate of women have a child using TCU-380A SMB IUD was 25.3%. This rate was lower than the study by Duong Thi Cuong about TCU 380A IUD-Netherlands (45.06%) [9].

Examining before IUD insertion, in this group of women using IUD TCU-380A SMB showed 17 women had bacterial vaginosis (3.66%). Vaginitis cases have been treated and then insert IUD. The rate of vaginitis before insert - 380A IUD TCU's research SMB was lower than Nguyen Van Tuong TCU 380A-Canada IUD (10.92%) in 2001 [18]. Today women have a qualification higher genital hygiene so the rate of gynecology infections than ever before. On

the other hand when selecting study subjects, group of study have removed all cases with gynecological inflammation history, so the rate of vaginitis of the study was low.

4.2. Effective contraception and failure rates

Table 4.1. Compare the effectiveness contraceptive of TCu 380A among authors

Authors	Not pregnancy		Pregnancy	
	n	%	n	%
Cole and collaborators, 1985 [29] (n=181)	180	99,45	1	0,55
Irving Sivin and collaborators, 1997 [34] (n=298)	297	99,66	1	0,34
Nguyen Van Tuong, 2000 [18] DCTC FaI (n=356)	351	98,60	5	1,40
Nguyen Van Tuong, 2000 [18] DCTC FEI (n=350)	346	98,86	4	1,14
Nguyen Van Tuong, 2000[18] DCTC Canada (n=357)	352	98,60	5	1,40
Duong Thi Cuong, 1995 [10] DCTC Hà Lan (n=2029)	2015	99,30	14	0,7
NHOG, 2005, DCTC TCu 380A- SMB (n=465)	465	100	0	0
NHOG, 2008, DCTC TCu 380A- SMB (n=1370)	1370	99,99	2	0,01

The effectiveness of the TCU 380A IUD-SMB was 99.99% , which equal the study of Nguyen Van Tuong with TCU 380A-Fai IUD (98.60%), Duong Thi Cuong with TCU 380A IUD- Netherlands (99.30%) and research of Cole

and collaborators in 1985 on 181 cases using TCU 380A IUD showed the effectiveness of contraception was 99.45%. Effective of author Irving Sivin and collaborators in 1997 at 298 cases insertion TCU 380A IUD was 99.66%. Pregnant with IUD provision: the rate of about 0.5% -5% [4].

The effectiveness of the TCU 380A IUD-SMB equivalent of efficiency Tcu 380A IUD was be researches and used in Viet Nam in family planning program because of the high efficiency of contraception. For this type of IUD without active ingredients such as frozen, and hormonal contraceptives effectively compete around 95-96%. But TCU 380A IUD types of contraception effectively implement about 99%. IUD is the most popular contraceptive in our country today. With highly effective contraception contributed to the reduction of birth, lead to brought economic benefit to the development of country [2].

4.3. Side effect and the safety

Table 4.2. Compare side effects of TCU 380A IUD after 12 months

Side effect and hazard	TCu 380A SMB (n=449)		TCu 380A Hà Lan** (n=2029)		TCu 380A FaI* (n=356)		TCu 380A FEI* (n=350)		TCu 380A Canada* (n=357)	
	n	%	n	%	n	%	n	%	n	%
Menorrhagia	15	3,34	99	4,90	22	6,18	24	6,86	22	6,16
Vaganitis	17	3,79	4	0,20	8	2,25	8	2,29	20	5,60
Irregular menstrual	39	8,69	182	9,03	-		-		-	
Stomache, backache when having menstrual	3	0,67	53	2,60	20	5,61	23	6,58	16	4,48
IUD slipped	0		32	1,60	22	6,18	26	7,43	35	9,8

* Notes: Data study by Van Tuong Nguyen in 2000 [18]

** Duong Thi Cuong's figures in 1995 [10]

Afer 12 months, the rate of women have menorrhagia when using TCu 380A-SMB IUD was 3,34%.

Menstrual pains: pain in the abdominal region when menstruating, switch to non-copper IUDs in these cases.

Menstrual disorders: the most common side effect encountered when using IUD, it claims 10-15% of the cases of compulsory IUD removal in the first year of use.[4].

The proportion of women have menorrhagia in this study was lower than ones in other studies in the world (Farr and Amatya was 5.6%) [32] and much lower than with research in Vietnam: Duong Thi Cuong with TCU 380A IUD was 4.9%-Holland, Nguyen Van Tuong with IUD-Fai was 6.18%, FEI IUD 6.68%, Canada IUD was 6,16%.

Although the proportion of women have menorrhagia when using SMB co-380A TCU IUD from 1.8% to 2.5% after 6 months use and after 12 months of use. This difference is not statistically meaningful and in the safety limits allowed. The proportion of women have menorrhagia in this study was lower than ones in other studies of other authors as described above. So Vietnamese women can use SMB-380A TCU IUD for their give birth needs. On the other hand, menorrhagia may affect the health and daily activities of the user. There are many subjects continued to use the TCU 380A IUD after treated menorrhagia. This rate was 6 per 15 women in 12 months.

After 12 months using TCU 380A-SMB IUD, the proportion of women having regular menstrual period was currently 87.5% after 6 months and 90.6% after 12 months. A change in menstrual cycle from 30-35 days without affecting health but only changed a little life activities of IUD users.

The rate of women have vaginitis during use of IUD TCU-380A SMB was from 6.8% to 7.9%. This rate is not much different with some other studies in Vietnam. Results' research of Nguyen Van Tuong, the rate of vaginosis when TCU 380A IUD Fai was 2.25%, 2.29% of FEI IUD, Canada IUD was 5.6% [18] and with the Duong Thi Cuong with TCU-380A IUD Netherlands was 0.2%. Bacterial vaginosis : a complication that can cause infertility, the rate of about 3-9%.

Causes of the vaginitis are bacterial, candidiasis and trichomonas. Rate causes of vaginitis in the group using TCU 380A-SMB IUD after 12 months from 0.22% -2.0%. This rate was lower than research results of Le Bach Quang (causes of vaginitis by candidas was 14%, 5.5% vagina by trichomonas) and of Nguyen Van Tuong (8.6% of vaginitis by cadidas, 0.2% of vagina by trichomonas) [16] [18].

The rate of women vaginitis before TCU 380A -SMB IUD insertion was 3.66% and the rate of bacterial vaginosis after 12 months was 6.8%. Do not differ much on the proportion of vaginitis before and after the installation of two types of TCU-380A SMB IUD. It was indicated that the use of IUD TCU-380A SMB does not have any effect on the level and status of vaginitis.

Level of vaginitis and vaginitis caused when using TCU 380A IUD-SMB is lower than other studies in Vietnam and the world. The rate of vaginitis may lower because of the selected subjects closely, otherwise Vietnamese women today there has been progress in sanitation, living, protect the environment better and medical workers has had much experiences while using IUD in family planning programs.

Sub- Pelvic pain: commonly experienced as the uterus contracts when a strange subject is present, treated by using painkillers in the first few months. Sometimes contraction of the uterus can expel the IUD.

After 12 months, the rate of women have hypogastric abdominal pains and backache need to untie TCu 380A-SMB IUD was 0,1% to 0,5%. This rate was much lower than studies of Nguyen Van Tuong at TCU 380A IUD-Fai (5.61%), FEI IUD(6.58%), Canada IUD(4.48%) [18] and Duong Thi Cuong TCU 380A Netherlands IUD(2.6%) [9].

After 12 months, the group's study has found seven cases of IUD slip during the first year of use. Factors affect IUD fell: Factors affecting IUD slip: age, time of giving birth, type of IUD, inserter's experience, placement time [3]. Time insertion and remove the TCU 380A IUD: IUD insertion at the time of last menses because the cervical opening is slightly dilated during this time, making insertion easier and equal important women had not pregnancy. IUD should not be inserted immediately after giving birth because of fell IUD. IUD could inserted after giving birth at least 8 weeks and abortion.[4].

Timing remove TCU 380A IUD: IUD could be in uterus from 5 to 10 years, if type of IUD contain hormone (Progestatif) must be replaced sooner[4].

There has case have ectopic pregnancy. IUD prevents the zygote from nesting in the uterine cavity, but cannot prevent it from nesting outside the cavity. However until now no study has made sure that IUD causes ectopic pregnancy [4].

A case of IUD IUD into abdomen: can be right when inserting or gradually over time.

Holing in the uterus: very little experience rates of approximately 1.2‰ insertion, if detected immediately after insertion and treatment of IUD uterus was preserved. Hazard depends on the time of IUD, posture uterus, especial experience of the technical of person who inserted. In our study no case with a hole in the uterus.

The rate of women had regular menstrual was very high (90.6%). The rate of women have vaginitits. The rate of complications and side effects of the IUD was very low. Research results showed that TCU 380A IUD safe for users.

Due to the high effective contraception, birth control needs to reach our users and meet the requirements of family planning programs, the status of irregular menstruation and menorrhagia in safety allows, should deliver widely used type of Tcu-380A IUD in our country, which suitable with safety....for protect mother and child.

4.4. Assess the rate of acceptance and give up

4.4.1. The rate of give up using TCU 380A IUD

Table 4.3. Compare give up and give up reason for TCU 380A IUD

<i>Give up reason</i>	TCu-SMB IUD	TCu-Farr *** IUD	TCu-FaI * IUD	TCu-FEI * IUD	TCu-Canada* IUD	TCu-Netherlands ** IUD
	%	%	%	%	%	%
Pregnancy	0,14	0,40	1,40	1,14	1,40	0,70
Menorrhagia	1,94	5,60	6,18	6,68	7,00	4,90
Hypogastric abdominal	0,64	-	5,61	6,58	4,48	2,60
Vaginitis	6,8	-	2,25	2,29	5,60	0,20
Change another contraceptive	0	1,20	5,98	2,16	4,20	6,80
Tụt DCTC	0,5	3,20	6,18	7,43	9,80	1,60
Other reasons (desire for more children...)	0,1	3,30	0,84	1,43	1,40	1,10
<i>General of rate give up</i>	<i>3,44</i>	<i>13,70</i>	<i>28,44</i>	<i>27,71</i>	<i>43,40</i>	<i>17,90</i>

*Note: * Data of Nguyen Van Cuong's research [18], ** Data of Duong Thi Cuong research[9], *** Data of Farr va Amalya [32].*

After 12 months, the proportion of women gave up continue to use the TCU 380A IUD-SMB was 3.44%, lower than the research by Nguyen Van Tuong with TCU 380A -Fai IUD was 28.44 %, TCU 380A IUD was 27.71%-FEI, TCU 380A -Canada IUD was 43.40%. Duong Thi Cuong's research showed that the proportion of women give up was 17.90% and 13.70% of Farr and Amalya. The rate of women give up TCU 380A SMB IUD was low because of women in need of practise family planning and consultation for contraceptive IUD effectively, otherwise subjects used IUD in research is voluntary.

Cause subjects give up TCU 380A-SMB IUD was mainly due to menorrhagia, was be treated. After 12 months, the rate of give up TCU 380A IUD because of having menorrhagia was 1.14%. The proportion of women having menorrhagia was much lower than study of Duong Thi Cuong (4.9%) [9] and the study of Nguyen Van Tuong (TCU 380A -Canada IUD was 7.0%, TCU 380A -Fai IUD was 6.18%, TCU 380A IUD-FEI was 6.68%) [18].

The rate of women give up the hypogastric abdominal pain, backache when use the TCU 380A IUD was 0.5%. %age of women give up when using TCU 380A IUD may be low by subjects using advice and needing care in time when side effects during the study. However, gave up rates by the hypogastric abdominal pains, backache when menstruating. There is much lower compared with study by Duong Thi Cuong (2.6%) [9] and Nguyen Van Tuong (TCU 380A Canada IUD 4.48%; TCU 380A-Fai USD was 5.61%, TCU 380A-FEI IUD was 6.58%) [18].

After 12 months using TCU 380A IUD-SMB, the proportion of women give up because of other reasons (desire for more children, etc.) was 0.14%. If

the rate of gave up declines hit a low, the medical facilities should be well organized public consultation about contraception, family planning counseling and perform especially advice on contraception IUD use for each subject before IUD insertion.

4.4.2. Accept use TCU 380A -SMB IUD

Table 4.4. Compare adoption rate using TCU 380A IUD

Timing use	TCu-SMB IUD	TCu-Farr *** IUD	TCu-FaI * IUD	TCu-FEI * IUD	TCu-Canada* IUD	TCu-Netherlands ** IUD
	%	%	%	%	%	%
After 3 months	100	-	-	-	-	-
After 6 months	98	-	-	-	-	-
After 12 months	97	86,30	71,56	72,29	56,60	82,10

Notes: * research data of Nguyen Van Tuong [18], ** research data Duong Thi Cuong's [9].

*** Farr's research data and Amalya [32].

Adoption rate continue to use the SMB-380A IUD TCU after 6 months was 98% and after 12 months was 97% higher adoption. This rate was higher than study by Duong Thi Cuong (82.10%) [9] and Nguyen Van Tuong (continuation rates of use IUD -Canada was 56.60%) and the Farr and Amalya (86.30%). Adoption rate continue to use the TCU 380A IUD may be caused by high-SMB today most women understand the benefits of reducing by use PL including IUD is one of the contraceptive method modern, high efficiency, economic and convenient. On the other hand by the quality of customer care medical personnel are increasingly and most cases are limited to give up, such feeling tired or desire formore children or other reasons not affect health.

CONCLUSIONS

1. After 12 months using, the effectiveness of TCu 380A-SMB IUDs was very high (99.99%)
2. TCu 380A-SMB IUDs which is provided by SMB Company, is safety for customers and low prevalence side-effects in women (the rate of menorrhagia was 1.8%, vaginitis was 6,8% ; hypogastric abdominal pains, backache when menstruating was 0,1 %). And it also has harmless effect to reproductive health and life habitant of users.
3. The prevalence which accepts using TCu 380A-SMB IUDs, is high (97%). The prevalence of women who give up, is low (3,44%) and Vietnamese women accepts using DCTC TCu 380A-SMB in Family Planning.

RECOMMENDATIONS

1. With two-steps study shows that TCu 380A IUDs which is provided by Indian SMB Company, were high effect of contraceptive method, safe for users, low prevalence side-effects and give up, relevant with Vietnamese women and accepted. So that, it is possible to use TCu 380A IUDs for Vietnamese women in Family Planning.

2. In order to increase the prevalence of using contraceptive methods and reduce population raising, provide widely contraceptive methods, avoid exclusiveness and create best conditions for customers, recommend that government submits to import and distribute TCu 380A IUDs which provided by Indian SMB Company at national-wide.

3. Recommend that Indian SMB Company continue supporting budgets and co-operating with the NHOG to manager, monitor, and consult for customers are using TCu 380A IUDs by Company provided.

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