

## **IUGA FELLOWSHIP FINAL REPORT:**

**Name of Fellow:** DEBJYOTI KARMAKAR

**Dates of Fellowship:** December 2013 – November 2014

**Host site, host name, and contact information:**

Aberdeen

Program Director: Dr Abdel-fattah

Department of Obstetrics and Gynaecology, University of Aberdeen/NHS Grampian

**Title of research study and all co-investigators:**

LONG-TERM OUTCOMES (8-YEARS) FROM THE PROSPECTIVE RANDOMIZED CONTROL TRIAL OF TRANS-OBTURATOR TAPES FOR STRESS INCONTINENCE IN WOMEN (THE ETOT STUDY)

Investigators: M Abdel-fattah, D Karmakar , A Mostafa.

**Detailed summary of research study**

- Objective was to assess the long term (LT) outcomes following TO-TVT and to compare the effectiveness of inside-out versus outside-in approaches.
- This was a long-term follow-up of the E-TOT study, a randomized controlled trial (RCT) of 341 women; conducted between April 2005 and April 2007 in a tertiary urogynaecology centre in the U K.

*Debjyoti Karmakar*

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- Patients were randomized to undergo either TVT-O (Ethicon Inc., Somerville, NJ, USA) for the inside-out approach or TOT-Aris (Coloplast Corp., Minneapolis, MN, USA) for the outside-in approach, as a sole and primary continence procedure.
- This study was carried out after Ethics Committee clearance
- The median follow-up was 8yr 9months. The primary outcome was patient reported success rate as recorded on PGI-I; success was defined as “Very Much Improved” or “Much Improved” Secondary outcomes included further treatment for SUI, impact on women quality of life, sexual function, late complications, and risk factors for late failures.
- This LT follow-up was completed by 194 of the 341 women (56.89%).
- The overall patient-reported success rate was 69.59%, with no significant difference between the inside-out and the outside-in TO-TVT (Outside-in 69/171: 71.87% vs. Inside-out 66/170: 68.04% (P=0.561).
- Clinically significant improvement in women QoL, (defined as  $\geq 10$  points on the KHQ, was seen in 76.8 %. with no evidence of significantly statistical difference between both groups
- Sexual function was Improved in 60.91%; with no evidence of significant difference between both groups
- Twenty-five women (7.33%) underwent further surgical treatment over the entire follow-up.
- The E-TOT RCT LT follow-up is one of the largest and longest prospective reports of TO-TVT outcomes and shows a 70% patient-reported success rate for TO-TVT at 8-yr follow-up, with no significant differences between inside-out and outside-in approaches. There was a drop in patient-reported success rates between 1 and 8

*Abstract summary*

years however only 7% of women underwent further surgical treatment. , but overall success rates were high.

***List of all ensuing abstracts based on research study.***

1) LONG-TERM OUTCOMES (8-YEARS) FROM THE PROSPECTIVE RANDOMIZED CONTROL TRIAL OF TRANS-OBTURATOR TAPES FOR STRESS INCONTINENCE IN WOMEN (THE ETOT STUDY)

2) A NEW VALIDATED SCORE FOR DETECTING PATIENT-REPORTED SUCCESS ON POSTOPERATIVE ICIQ-SF: A NOVEL TWO-STAGE ANALYSIS FROM TWO LARGE RCT COHORTS. This was my original idea and further refined by Dr Abdel-fattah and patient cohorts derived from the ETOT(above study) and SITOT (Single incision trans-obturator tape ) study.

***(accepted as podium presentation for IUGA 2015 annual meeting : acceptance emails forwarded to Ms Grabloski)***

***Manuscript***

We have started preparing manuscripts for the accepted IUGA annual meeting podium presentations (TWO) with the assent of Dr Abdel-fattah and will submitted one version for the IUGA best paper bid and then build on it and submit to the IUJ journal.

*Abdel-hameed*

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***Clinical responsibilities and experiences. Provide details relative to clinical, surgical, or other responsibilities. Place your learned skills in context to your sought goals.***

This post had clinical commitment of 60-70% of my time, and provided me with experience in the management of a range of pelvic floor disorders at secondary and tertiary level. Thirty to forty percent of my time was dedicated to research which included one primary research along with involvement in the multi-centric SIMS RCT(single incision mini-sling versus standard sling) along with other research activities including systematic reviews and project proposals/grant applications. I have been trainee faculty in hands-on cadaver workshops in cystoscopy for gynaecologists. The fellowship had its clinical component accredited and logged through the RCOG(Royal College of Obstetricians and Gynaecologists) urogynaecology Advanced Training Skills Module(ATSM) under the North Of Scotland Deanery. This module provides the training framework to train towards being a gynaecologist with special interest in urogynaecology in the UK. My clinical commitments included :

- 1) Urogynaecology clinic: seeing patients both independently and under supervision
- 2) Urodynamics/one stop Urogynaecology clinic: seeing patients and urodynamic assessment both independently and under supervision. I have conducted independent registrar led Urodynamics/one stop Urogynaecology clinic.
- 3) Preoperative assessment of patients.
- 4) Minor and major urogynaecology cases: first assistant regularly, main surgeon on rotational basis with local urogynaecology trainees. My surgical experience includes surgery for prolapse and incontinence. Apart from retropubic and transobturator slings I also have had the opportunity to train in performing Single incision mini-slings(SIMS) under local anaesthesia as part of SIMS National RCT.

*Deborah Larnach*

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5) Post operative care.

6) I helped in the setting up and thereafter was the coordinator for the regional Urogynaecological MDT meeting (organized once a month)

This post also entailed providing oncall cover in emergency gynaecology and labour ward on a locum basis on the Senior Registrar tier

***Summary of what I have learned related to urogynecology since completing the fellowship and how I plan to apply this knowledge in future.***

I have realized Urogynaecology involves providing outstanding multidisciplinary service especially in quality of life domains of patients and this relies heavily on cutting edge research . My career aim is to have specialized training and expertise in urogynaecology as a subspecialty . I plan to continue my research interest and collaborations into pelvic floor disorders, with the ultimate aim of translating the relevant findings to my clinical practice to the benefit of the patients in my care. The fellowship gave me an insight into the functioning of a subspecialist urogynaecology tertiary set up with a significant clinical workload. It also exposed me to the research governance involved in high quality research. The fellowship reinforced my passion in this subspecialty and has made me a more complete gynaecologist by providing me with an opportunity to harness this special interest. My acquisition of skills in urodynamics and continence surgery will be especially crucial to my dream of helping to set up an accredited fellowship training programme in my country of origin, India as it gave me an idea of the resources need for such specialized provision of training.

***Strengths and weaknesses of the fellowship program:***

*Deepti Karmakar*

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**Strength:**

- ✓ Robust selection process which takes into account both experience and aspiration of the applicant
- ✓ One of its kind international fellowship and has enormous vision and potential to fuel interest in young doctors in this area
- ✓ Carries the vision of an expert panel of subcommittee members with emphasis on all round clinical-research fellowship
- ✓ Ideal platform and duration to gain special clinical and research skills.
- ✓ Emphasis on completion of one primary research project ingrained in the program

**Weaknesses**

- ✓ Lack of fellowship log book, I believe the education committee is looking at this after I suggested it in the interim report.

**Account of expenditure:**

- ✓ Medical registration for license to practise, etc : 500 pounds
- ✓ CPD activities ,workshop,courses:1000 pounds
- ✓ Travel to work : 100 pounds per month(1200 pounds)
- ✓ Monthly accomodation rent : 850 pounds per month(10200 pounds )
- ✓ Utilities and taxes: 300 pounds per month (3600 pounds)
- ✓ Food : 200 pounds per month(2400 pounds)
- ✓ Family Health and travel insurance:600 pounds
- ✓ Miscellaneous:2000 pounds

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*Deborah Hamaker*

15 March 2015

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Total 21500 pounds (32000 USD)

***Other comments***

I would like to sign off with a note of hearty thanks and gratitude for IUGA for providing me with this prestigious opportunity .I shall remain grateful to IUGA and shall try my best to repay by volunteering and helping IUGA in its activities in whichever possible capacity and opportunity. It has been a life changing experience for me.

I would like to see this fellowship grow even more robust and I believe that the fellowship will benefit from technical and financial support of country specific urogynaecology societies /colleges , so that more funding can be arranged while devolving the administration and oversight of the fellowship at a more local level with the IUGA maintaining quality control overall.

*Deborah Karmali*

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All in all it's a very good fellowship concept and is the ideal platform for young gynaecologists/urologists to develop skill sets which may not be available in their native country ,but the current fellowship funding may not be sufficient after registration, visa , flights etc. in most developed countries for a year given the economic climate and inflation. Hence all future aspirants should try to discuss possibilities of supplemental funding at a local level with prospective supervisors in advance or arrange educational loans from their home country before travelling.

It is also my humble suggestion that the IUGA should proactively organize 3 monthly oversight meetings (Skype/teleconference) between the education committee, fellow and supervisor to ensure smooth progression of fellowship and to ensure a personal development plan is in place for the fellow rather than just filing of one interim report. This would motivate both the fellow and the supervisor to achieve more in the given fellowship period. The IUGA should support sites where there is objective evidence of clearly documented pathways in place for immigration/visa (human resources) processing for the fellow, detailed job description including template weekly time tables and work hour regulations, hospital/subsidized accommodation, and departmental commitment to embed overseas fellows in their middle grade tier in a specific role. This is important as for most fellows it would be the first overseas job and this would help allay a lot of anxiety and insecurity.

The IUGA annual meetings should be used as opportunities to seek more prospective interested host sites to provide the fellowship under the umbrella of IUGA but with possibility of part local funding as such fellowships will succeed or fail depending on the available funding. This can also lead to allotment of the fellowship to more than one fellow a year.

*Deepti Karmakar*

15 March 2015



*Deepti Karmakar*

15 March 2015