Original article

Evolution of the TOT OUT/IN technique: retropubic TOT. Morbidity and 5-year functional outcomes

VINCENT BARBIER[1], CÉLINE DUPERRON[2], EMMANUEL DELORME[3]

[1,2] *Centre Hospitalier Universitaire François Mitterand, Service Urologie, Dijon, France*
[3] *Hopital Privé Sainte Marie, Service Urologie, Chalon-sur-Saône, France*

Abstract: Objectives: To describe the retropubic transobturator tape (TOTRP) technique for treating female stress urinary incontinence (SUI). To evaluate morbidity and 5-year functional outcomes. *Materials and methods:* A single-centre, observational, retrospective, single-surgeon study was carried out. The patients included had a TOTRP placed between 2009 and 2012. The originality of the technique is the horizontal transobturator and non-oblique route of the ancillary. The perioperative characteristics were recorded. The functional outcomes were evaluated pre-surgery and between March and April 2016 using the Urinary Symptom Profile (USP) questionnaire. *Results:* 88 patients were evaluated after 5 years. The lost-to-follow-up rate was 7.4%. No perioperative complications were found. There was no tape erosion, no pain over the 5 years. The SUI was improved in 92% of the cases and cured in 72.7% of cases. The de novo overactive bladder (OAB) rate was 15.9%. In patients presenting with pre-operative mixed UI, the SUI was improved in 100% of cases and cured in 63.6% of cases. The OAB was improved in 45.5% of cases. *Conclusion:* The TOTRP is associated with an absence of perioperative morbidity and no erosion in the long term. The TOTRP technique gives functional outcomes after 5 years that are similar to the data in the literature for the conventional TOT technique, whilst reducing morbidity.

Keywords: Functional Outcomes; Morbidity; Questionnaire Urinary Symptom Profile symptom; Retropubic TOT; Stress urinary incontinence.

INTRODUCTION

Mid-urethral sling implantation is the reference technique in female SUI surgery. It was Ulmsten that described the tension-free mid-urethral sling technique via the retropubic route (RPT) 1996[1]. The medium-term outcomes have demonstrated its efficacy[2]. According to the work done by Petros, the tape should be positioned under the middle third of the urethra away from the bladder neck[3]. We descried a variant of TVT, the TOT in 2001[4]. Since 2004, with the aim of reducing complications (perioperative perforation of organs, subsequent visceral tape erosion) and improving functional outcomes, we modified the technique to describe the TOTRP or horizontal TOT.

The aim of our study was to describe the surgical technique for implanting a TOTRP to treat female SUI and to evaluate the morbidity and 5-year functional outcomes.

MATERIALS AND METHODS

This observational retrospective study included patients who had undergone SUI surgery involving the implantation of a hypoelastic retropubic transobturator tape, Cyrene (Abiss, Saint-Etienne, France) between January 2009 and December 2012. Patients who had already undergone surgery for SUI or for pelvic floor dysfunction were excluded from the study.

Before the operation, the patients were comprehensively interviewed and the main characteristics compiled (age, body mass index, obstetric status, exposure to tobacco, diabetes, chronic constipation, hysterectomy). Bladder symptoms were evaluated using Urinary Symptom Profile (USP) scoring. This questionnaire was described by Haab F et al. [5] apice in 2007 and has been validated by the *Association Française d'Urologie* (AFU). Comorbidities were evaluated with the Charlson score. Each patient underwent an in-depth clinical examination as well as urodynamic testing.

IRB approval has not been considered necessary as the TOTRP is only a modification from the original TOT and not a new surgery procedure. Furthermore, all surgeries have been carried out by the same surgeon who performed the original TOT. He currently keeps on using this approach.

Surgical technique:

Two Allis clamps on each side of the urethral meatus expose the vaginal wall behind the urethra widely. The beginning of the incision is 5 mm from the meatus. It is a sagittal retro-urethral incision through the full thickness of the vaginal wall and must be wide enough to enable the insertion of a finger. The lateral dissection from the urethra must be between the fascia and the urethra, never between the fascia and the mucosa, because that increases the risk of vaginal erosion by the tape. The dissection stops before opening the perineal membrane, because the needle passing through the perineal membrane will act as a pulley directing the tape to the middle third of the urethra.

A punctiform cutaneous incision is made at the horizontal level between the urethral meatus and the clitoris, exactly against the external edge of the bone in the corner between the pubic bone and the ischiopubic ramus where the bone is narrowest. A straight needle is usually used, but it is possible to use a helical needle. The needle course is obtained by aiming for the urethral meatus with the tunnelling device. A finger is inserted as a sentinel inside the incision, lateral to the urethra. But the finger is right behind the pubic bone and higher we can avoid damaging the perineal membrane. The ball of the index finger in the vaginal incision is used to push the urethra back upwards and inwards, protecting it from the needle.

The horizontal course of the tunnelling device is in three steps:

- First step: strong contact with the ischiopubic ramus and follow the bone from inside to out.
- Second step: when the needle leaves the bone, immediately turn behind the bone and get a frank contact with the finger which is behind the pubic bone and not laterally under the ischiopubic bone branch. The blind needle passage is very short between the needle leaving the bone and coming into contact with the finger. This blind passage crosses the obturator muscles.
- Third step: the needle is pushed through the perineal membrane and it is driven by the finger inside the vaginal incision. The needle perforates the perineal membrane lateral to the urethra in the acute angle between the ischiopubic ramus and the urethra, close the meatus to come up against the middle third of the urethra.

The aim of this movement is to trace a perineal trajectory with the surgical instrument whilst remaining below the superior fascia of the Levator Ani muscle and to drive the device lateral to the middle third of the urethra. Once complete, it is advisable to look and check that the vagina has not been pierced by the tunnelling device. The tip of the tape is fixed to the tip of the needle and then drawn into place. Adjustment of the tape behind the urethra is difficult. The adjustment technique depends on the elasticity of the tape. There is no easily reproducible technique to propose. The only advice that we can give is to always use the same kind of tape.

With a low-elasticity tape with a strong grip, such as CYRENE®, a visible space must be left between the tape and urethra. The technique to adjust CYRENE is very reproductive. The right angle forceps makes a plication of the middle of the tape and there is an urethral catheter 16 french. The arms of the tape are pull strongly. When the tape is against the urethra, the forceps is remove and the adjustment of the tape is fit. At the beginning of this series we did not do this technique of adjustment that explain the voiding dysfunction we had.

With a high-elasticity tape, the tape must rest against the urethra with no pressure. The excess tape outside the skin is cut off. The vaginal incision is closed with a few simple absorbable sutures. The obturator incisions do not need to be sutured, but care should be taken to separate the skin from the tape. The anatomical and surgical study confirms that the horizontality of the transobturator route of the needle participates in the positioning of the needle in the perineal space between the levator muscle and the perineal membrane, corresponding to the middle 1/3 of the urethra (Figure 1).

The perioperative complications and immediate post-operative complications during the hospital stay were analysed. Later complications were recorded: recurrent urinary infections, overactive bladder (OAB) and how they were treated, erosion-type complications, repeat operations, the appearance of chronic pelvic and perineal pain. The patients were contacted between March and April 2016. They were given the USP questionnaire to complete to evaluate the long-term functional outcomes. The results of the USP questionnaire done after the surgery were compared to those of the questionnaire done prior to surgery. To describe as precisely as possible the intensity of the symptoms, the patients were divided into three groups according to their SUI, OAB and dysuria scores. SUI was defined as mild if the score was below 3, moderate if the score was between 4 and 6 inclusive and, finally, severe for a score between 7 and 9. Post-surgery, SUI was considered as cured if the score was 0 or 1. OAB was defined as mild if the score was below 7, moderate if the score was between 8 and 14 inclusive and, finally, severe for a score between 15 and 21. Dysuria was defined as mild if the score was below 3, moderate if the score was between 4 and 6 inclusive and, finally, severe for a score between 7 and 9. The values for the quantitative variables were expressed as mean +/-standard deviation. The values for the qualitative

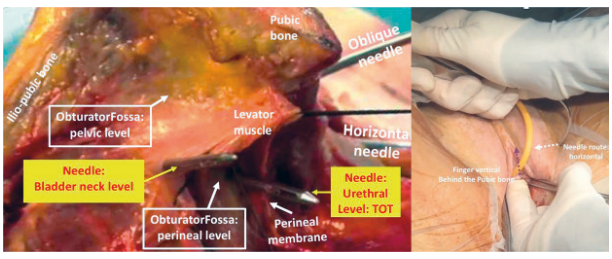

Figure 1. – Anatomic study. Needles routes Retropubic TOT and Oblique TOT.

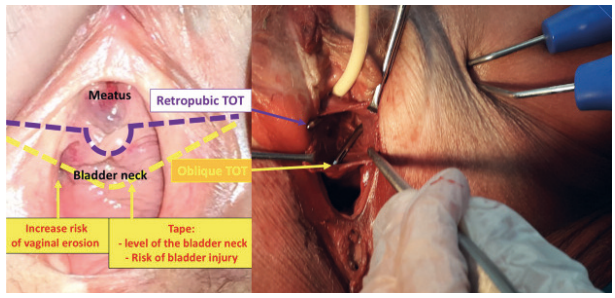

Figure 2. – Anatomic study . The positioning of the tape.

variables were expressed as a number of patients per group, frequency (%). Difference between score before surgery and 5 years after surgery were assessed using chi2 Mantel Haenszel's test for categorical variables. All statistical analysis were performed with SAS version 9.4.The significance was evaluated by calculating value p. A result was judged significant if $p \leq 0.05$.

RESULTS

95 patients were implanted with the TOTRP to treat SUI between 2009 and 2012. They had never been operated on before for urinary incontinence or pelvic floor dysfunction. Out of 95 questionnaires sent out to patients between March and April 2016, 70 were completed by hand. 18 patients were re-contacted by telephone and the questionnaire was then completed orally. 7 patients could not be contacted. 88 patients were therefore included in our study. The response rate was 92.6% and the lost-to- follow-up rate was 7.4%. The average duration of follow-up was 59 months. While filling in their applications forms, patients gave both written and oral agreements to participate to this study. This is notified in their medical history. The average age of our population was 54.7 years, with an average BMI of 27 kg/m2. 63.2% of the patients had a BMI of ≥ 25, including 3 patients with morbid obesity. Regarding their obstetric history, the women had had on average 2 vaginal deliveries, 9 were nulliparous. Only 12.6% of our patients had been exposed to tobacco. 8.4% of the patients suffered from diabetes. 12 patients, or 13.6% had undergone a hysterectomy, 8 for benign causes (uterine fibroid, endometriosis) and 4 due to endometrial cancer. 33 patients, or 37.5% of the sample had chronic constipation. Significant rachialgia was found in 36 patients, or 40.9% of the sample. Most of the patients (75.8% of the sample) had a low score on the Charlson comorbidity index, between 0 and 2 inclusive. On clinical examination, the patients all presented SUI with jet leakage on coughing corrected by urethral support manoeuvres. All the patients had cervico- urethral hypermobility, none had an immobile urethra. The urodynamic test results were not prejudicial to operating in any of the patients. None of the patients had a dysuric curve in the uroflow test with a maximum flow rate on average of 30 ml/s. None of the patients had significant posit-void residual urine. There were no cases of sphincter deficiency. The average maximum urethral closure pressure was 68cmH20. Finally, all the patients had normal bladder compliance. There were no perioperative complications (organ perforation, haemorrhaging). Six patients (6.8% of the sample) had immediate post-operative dysuria with post-void residual urine of over 80 cc on 2 occasions. They were successfully treated by surgical loosening of the tape between D3 and D6. No tape erosion was found in our series post- surgery. Four patients (4.5% of the sample) had recurrent lower urinary tract infections in the 5 years following surgery. 12 patients were given anticholinergenic drugs (AC) for overactive bladder in the first two years

TABLE 1. Distribution of patients according to intensity of pre-operative and long-term post-operative SUI, OAB and dysuria.

score	pre-operative n (%)	post-operative n (%)	P value
SUI			< 0.0001*
mild	0 to 3	0 (0)	73 (83)
moderate	4 to 6	40 (45.5)	11 (12.5)
severe	7 to 9	48 (54.5)	4 (4.5)
OAB			0.0328*
mild	0 to 7	77 (87.5)	67 (76.1)
moderate	8 to 14	11 (12.5)	19 (21.6)
severe	15 to 21	0 (0)	2 (2.3)
Dysuria			0.7763*
mild	0 to 3	83 (94.3)	83 (94.3)
moderate	4 to 6	5 (5.7)	4 (4.5)
severe	7 to 9	0 (0)	1 (1.2)

* Mantel-Heanszel Chi2 test

after surgery. Among these 12 patients, due to OAB refractory to AC treatment, two patients underwent surgery (Botulinum toxin injection and sacral neuromodulation). Only one patient was still taking an AC at the time of the final evaluation. In most cases, the AC was stopped in the year after its introduction. 3 patients did not see an improvement in the SUI by the operation in the immediate post-operative period. They benefited from a successful surgical plication of the tape within two years of the initial operation. None of the 88 patients had chronic pelvic and perineal pain immediately after the operation or in the longer term. The patients were divided into 3 groups according to the intensity of their SUI as defined by the score calculated using the USP questionnaire pre-surgery and post- surgery (Table 1).

Pre-surgery, 40 patients had moderate SUI, 48 had severe SUI. 5 years after surgery, 73 patients had mild SUI or it was cured, 11 had moderate SUI and 4 had severe SUI. The distribution of the patients in the different subgroups between pre- operative status and post-operative status was significantly different (p<0.0001). The patients were considered as having improved when they were in a lower intensity SUI group after surgery, namely 81 patients. The improvement rate for SUI after 5 years was therefore 92%. Four patients (4.5% of the sample) were in the same group post-surgery and were considered as not having improved. Three patients (3.5% of the sample) were in a group with a higher score post-surgery and had therefore suffered either a recurrence or a worsening of the SUI after 5 years. The patients were considered as cured and continent when they had an SUI score between 0 and 1 inclusive. 50 patients had a score of 0, 14 a score of 1. The cure and continence rate for our series was therefore 72.7% after 5 years. The patients were also divided into 3 groups according to the intensity of their OAB as defined by the score calculated using the USP questionnaire pre-surgery and post-surgery (Table 1).

The pre-operative OAB rate (moderate OAB or severe OAB) was 12.5% and therefore concerned 11 patients. Post-surgery, 19 patients had moderate OAB, two had severe OAB. The post-operative rate was therefore 23.9%. Among these 21 patients, 14 patients had non-significant mild pre-operative OAB. They therefore presented de novo OAB at 5 years, that is 15.9% of our sample. The distribution of the patients in the different subgroups between pre-operative status and post-operative status was not significantly different (p=0.033). The dysuria scores calculated from the USP questionnaires completed pre-surgery and at long-term follow-up after surgery are presented in Table 1. Of the 5 patients who had moderate or severe dysuria post-surgery, 3 did not present pre-operative dysuria. One patient presented de novo dysuria associated with early recurrence of SUI. One patient presented de novo dysuria associated with de novo moderate OAB. One patient presented de novo dysuria associated with de novo severe OAB refractory to anticholinergenic treatment. The distribution of the patients in the different subgroups between pre-operative status and post-operative status was not significantly different (p=0.78). 11 patients in our series had mixed urinary incontinence pre-surgery. 63.6% of them were cured of the SUI, and 100% were improved. The OAB was cured in 45.5% of cases, unchanged in 45.5% of cases, and worse in 9% of cases. Thus, the treatment of mixed UI by implanting a tape was very effective in correcting the SUI and moderately effective in correcting OAB.

TABLE 2. Studies evaluating long-term outcomes with TOTs.

Authors	n	Lost to follow-up (%)	Follow-up (years)	Continence (%)	Improvement satisfaction (%)	Exposure (%)	De novo OAB (%)	Revision surgery for recurrence (%)
Abdel-Fattah et al. (6)	341	30	3	73,1	NC	1,8	NC	6
Rajendra et al. (7)	419	55	3	NC	89,7	2,4	NC	NC
Schierlitz et al. (8)	164	10	3	NC	NC	NC	NC	20
Lienhart et al. (9)	331	24	7	72	80	0,3	27	0,9
Our study	88	7,4	5	72,7	92	0	15,9	3,4

DISCUSSION

Compared to the main series in the literature dealing with the long-term outcomes of TOT (Table 2), our sample was smaller[6,7,8,9]. Our study was carried out in a single centre by a single surgeon with strict inclusion rules. However, the lost- to-follow-up rate was much lower (7.4%) than in the studies previously mentioned and others[2,10,11], which gives the study more force. The main reasons why patients did not respond to the contact by letter were a lack of time, forgetfulness and a questionnaire deemed too complicated to complete. The average follow-up time in our study was 5 years. The cure rate in our series was 72.7%, which is in line with the average in the literature[6,9]. The subjective success/improvement rate found in the published studies on the transobturator route is between 64 and 73% inclusive[6,12]. A recent study by Karmakar et al[13] evaluated the functional outcomes over a period of 9 years. Their study concerned a series of 341 patients divided into 2 groups, "inside/out" (TVT- 0) and "outside-in" (TOT). The response rate was low at 67.8%. Success was evaluated at 80% after 1 year with no significant difference between the 2 groups. At 3-year follow-up continence was 73.1%, at 9 years 71.6%. The rate of surgical revision in their study was 7.9%. The erosion rate was 4.5%. In our series, the de novo OAB rate was 15.9%. We find de novo OAB rates in the literature of between 9 and 27% inclusive[9,11,13,14].

The rate of surgical revision for recurrence of SUI in our series was 3.4%. In fact 3 patients underwent successful plication of the tape some time after the operation. In the literature, after an average follow-up period of 5 years, the outcomes are quite conflicting, with revision rates between 0.9 and 14% inclusive[6,9,11,15]. Six patients presented post-operative dysuria which required early surgical revision to loosen the tape. This rate is higher than in the literature. However, our effectiveness criteria on the return of micturition were demanding. Indeed, if PVR was greater than 80 cc on 2 occasions on D1 then this was taken as an indication to loosen the tape. The cause of this

initial dysuria may be secondary to the TOTRP technique, to an excessive surgical adjustment or to the characteristics of the MUS (low elasticity and good grip of the tape in the tissues). The early loosening of the tape performed in our series successfully treated the dysuria in all cases without altering the outcome on continence. It seems to us that the best treatment for post-operative dysuria is prevention.

This requires pre- operative detection of inadequately contractile bladders and perfect adjustment of the tape during the operation. This adjustment depends on the type of tape used, mainly its elasticity. The usual treatment for post-operative dysuria in patients not known to be dysuric before the operation is the sectioning of the tape[16]. Loosening seems to be more effective if it is done early[17]. During the operation no patients had complications such as haemorrhaging, perforation of the urethra, bladder, vagina. We had no visceral complications (bladder, urethral, vaginal erosion) in our series. Furthermore, an earlier study also evaluating TOTRP with 185 patients followed up after 3 years did not report any vaginal or visceral erosion[18]. In the literature, the long-term erosion rate is between 2 and 6% inclusive[7,9]. The particularity of the TOTRP technique was the initial route of the tape, horizontal whereas in the original technique, the route was initially oblique. With the TOTRP technique, keeping the tape under the middle 1/3 of the urethra, limiting the risk of slipping down towards the bladder neck, is achieved by two technical tricks:

• The horizontal route of the needle, which crosses the obturator muscles horizontally, corresponding to the middle 1/3 of the urethra.

• The needle going through the perineal membrane in the angle between the urethral meatus and the ischiopubic ramus.

The positioning of the tape at the right level in relation to the urethra seems to be decisive in limiting functional disorders (persistent incontinence, chronic pain) and reducing the risk of perforating the bladder or the urethra. The anatomical study confirms our clinical outcomes (figure 2). On the one hand the sling straps are retro- and subpubic, and therefore do not cross the latero-urethral vaginal fornices; there is therefore no risk of lateral vaginal erosion. Precise dissection in the plane between fascia and urethra allows a fascia-mucosa suture of the vaginal incision, reducing the risk of median vaginal erosion.

CONCLUSION

The TOTRP is associated with an absence of perioperative morbidity (urethral, bladder, vaginal perforation) and no risk of erosion in the long term. After 5 years' follow-up, SUI was improved in 92% of the women. 72.7% of the patients were continent 5 years on. De novo OAB concerned 15.9% of the patients at 5-year follow-up. The TOTRP technique therefore leads to lower morbidity and functional outcomes that are identical to the conventional TOT OUT/IN technique. Our results will need to be confirmed by larger multi-surgeon series.

DISCLOSURE STATEMENTS

We obtained oral and written informed patient consents (notified in the medical file). Doctor Delorme is an expert for the Abiss company.

REFERENCES

1. Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J, 1996; 7: 81-5.
2. Svenningsen R, Staff AC, Schiotz H, Western K, Kulseng-Hanssens. Long-term follow-up of tension-free vaginal-tape (TVT): an observational multicentre study from a national incontinence registry. Abstract 253, ICS 2012.
3. The Female Pelvic Floor. Function, dysfunction and management according to the Integral theory. Second Edition. Peter Petros. Springer Medizin Verlag Heidelberg 2007.
4. Delorme E. Transobturator urethral suspension : mini-invasive procedure in the treatment of stress urinary incontinence in women. Prog Urol 2001; 11: 1306-13.
5. Haab F, Richard F, Amarenco G, Coloby P, Arnould B, Benmedjahed K, Guillemin I, Grise P. Comprehensive Evaluation of Bladder and Urethral Dysfunction Symptoms: Develpment and Psychometric Validation of the Urinary Symptom Profile (USP) Questionnaire. Prog Urol 2008; 71, 4: 646-656.
6. Abdel-Fattah M, Mostafa A, Familusi A, Ramsay I, N'Dow J. Prospective randomised controlled trial of transobturator tapes in management of urodynamic stress incontinence in women: 3-year outcomes from the evaluation of transobturator tapes study. Eur Urol 2012; 62: 843-51.
7. Rajendra M, Han HC, Lee LC, Tseng L, Wong H. Retrospective study on tension-free vaginal tape obturator (TVT-O. Int Urogynecol J 2012; 23: 327-34.
8. Schierlitz L, Dwyer PL, Rosamilia A, Murray C, Thomas E, De Souza A, Hiscock R. Three year follow-up of tension-free vaginal tape compared with transobturator in women with stress urinary incontinence and intrinsinc sphincter deficiency. Obstet Gynecol 2012; 119: 321-7.
9. Lienhart J, Vautherin R, Grisard-Anaf M, Frobert J-L. Analyse à 7 ans d'une série de 331 bandelettes I-Stop trans-obturatrices implantées pour traitement de l'incontinence urinaire d'effort de la femme. Progrès en urologie (2014) 24, 750-756.
10. Nilsson CG, Palva K, Rezapour M, Falconer C. Eleven years prospective follow-up of the TVT procedure for the treatment of stress urinary incontinence. Int Urogynecol J 2008; 19: 1043-7.
11. Groutz A, Rosen G, Cohen A, Gold R, Lessing J, Gordon D. Ten-year subjective results of the retropubic tension-free vaginal tape for treatment of stress urinary incontinence. J Minim Invasive Gynecol 2011; 18 (6): 726-9.
12. Narang S, Han HC, Lee LC, Wong HF. 5 years outcome of mid-urethral slings TVT vs TVT-O: a retrospective comparative study. Int Urogynecol J 2012; 23 (suppl. 2): S43-244.
13. Karmakar D, Mostafa A, Abdel-Fattah M. Long term outcomes of transobturator tapes in women with stress urinay incontinence: E-TOT randomised controlled trial. BJOG 2017; 124 (6): 973-981.
14. Serati M, Ghezzi F, Cattoni E, Braga A, Siesto G, Torella M et al. Tension-free vaginal tape for the treatment of urodynamic stress incontinence: efficacy and adverse effects at 10-year follow-up. Eur Urol 2012; 61: 939-46.
15. Angioli R, Plotti F, Muzii L, Montera R, Panici PB, Zullo M. Tension-free vaginal tape versus transobturator suburethral tape: five year follow-up results of a prospective, randomised tiral. Eur Urol 2010; 58: 671-7.
16. Game X, Soulie M, Malavaud B, Seguin P, Vazzoler N, Sarramon JP et al. Treatment of bladder outlet obstruction secondary to suburethral tape by section of the tape. Prog Urol 2006; 16: 67-71.
17. Long CY, Lo TS, Liu CM, Hsu SC, Chang Y, Tsai EM. Lateral excision of tension-free vaginal tape for the treatment of iatrogenic urethral obstruction. Obstet Gynecol 2004; 104: 1270-4.
18. Castaings T, Abello N, Delorme E. Prospective study on 185 females with urinary incontinence treated by an outside-in transobturator suburethral sling. Pelviperineology 2012; 31: 18-23.

Correspondence to:

Vincent Barbier
14 rue Gaffarel - Dijon 21079 Bourgogne - France
vincent.barbier@chu-dijon.fr vincebarberr@yahoo.fr

Céline Duperron celine.duperron@chu-dijon.fr,
Emmanuel Delorme delormee_2000@yahoo.fr