National Institute for Health and Care Excellence

IP1556 Laparoscopic ventral mesh rectopexy for internal rectal prolapse

IPAC 12/04/18

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Patient		Hello I wish to have a say as a patient badly injured after LVMR which was performed without my knowledge of the inclusion of mesh. In fact none of the procedure was explained to me. (Within a month of the op I had to have a sigmoid colectomy which I believe compromised the original LVMR). I found out about mesh was used after I was left in severe pain after apparent failure of the op within the year. After EUA I was told the mesh had snapped and I needed repair. Exactly year later underwent an op which I believed to be a repair. Only to be told they couldn't find half of the mesh. I have now found out they added a different mesh and unbeknown to me when they carried out STARR surgeons also did post colporrhaphy and anterior Sacrocolpopexy. Following these surgeries I suffered increasing pains, everything felt too tight and I suffered constant blockages. Eventually I had an ileostomy and developed parastomal hernia treated with yet more mesh. Finally I had my colon removed but my health has declined with constant obstruction episodes regular bleeds through my stoma and the odd abscess and regular bouts of cystitis. The pains are so severe I cannot walk very far and I'm left housebound. Far from the outdoor wildlife photographer I used to be now 10 years ago.	Thank you for your comment. The Committee very much welcomes hearing from patients and has considered your experience and views. This has contributed to their understanding of how serious the adverse events of this procedure can be. The IP Programme issues guidance on procedures after having reviewed the best existing evidence on its safety and efficacy. The Committee has considered that there is limited evidence on the efficacy and safety of laparoscopic ventral mesh rectopexy for internal rectal prolapse and has recommended special arrangements for clinical governance, patient consent

			All I have had from the surgeon is denial stating low incidence so have no proper help my GP has tried to refer me for proper specialist care. Unless Rectopexy complications are recognised I see no future for me getting proper & urgently needed healthcare. I personally believe metal fixation (pains like moving barbed wire or cheesewire) makes pains & illness worse as the mesh shrinks and twists. I am a member of 2 support groups (1 specifically for rectal prolapse and inssusseption) with more and more injured patients coming forward daily. I was told it was Gold Standard and I was the only one whose mesh went missing I was unique. Unfortunately I now know 1000s of others have been told that too. There are so many more with stories like mine after rectopexy trying desperately to get badly needed specialist care. Thank you for this opportunity to tell you some of my rectopexy story. Kind Regards [redacted]	(including information on types of mesh and complications) and audit or research. The Committee has also recommended that patient assessment and treatment should be done by a multidisciplinary team specialised in the management of rectal prolapse, including appropriately trained surgeons. In addition, the Committee recommended that data from patients having the procedure should be entered into the British Pelvic Floor Society database and any mesh related complications reported to the MHRA. IPAC also added a committee comment on patient experience with this procedure in section 3.8 of the guidance.
2	Consultee 2 Patient		I have had this procedure done twice by suspended [redacted] Surgeon Mr [redacted]. I have suffered life changing consequences since these procedures. I'm 16 weeks into recovery for mesh removal, after it was found that it was fixed to sacrum instead of promontory and had eroded into small bowel and	Thank you for your comment. The Committee very much welcomes hearing from patients and has considered your experience and views. This has contributed to their understanding of how serious

			rectum. I have ended up disabled with an ileostomy and am in narcotic pain relief. Please stop this procedure and ban the mesh. I hope Mr [redacted] never operates on another patient. [redacted] Sent from my [redacted]	the adverse events of this procedure can be. The IP Programme issues guidance on procedures after having reviewed the best existing evidence on its safety and efficacy. The Committee has considered that there is limited evidence on the efficacy and safety of laparoscopic ventral mesh rectopexy for internal rectal prolapse and has recommended special arrangements for clinical governance, patient consent (including information on types of mesh and complications) and audit or research. The Committee has also recommended that patient assessment and treatment should be done by a multidisciplinary team specialised in the management of rectal prolapse, including appropriately trained surgeons. In addition, the Committee recommended that data from patients having the procedure should be entered into the British Pelvic Floor Society database and any mesh related complications reported to the MHRA.

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3	Consultee 3 Patient		The problems are so agonisingly painful, is there a comment page I can list the....problems.....it should be withheld until full registration of each Mesh patient is listed and survey sheet sent out...that may include patients who were Lucy, to have a successful outcome....but what does their future hold. Your chance is now, otherwise for years and years to come men and women will suffer...NICE will loose all patient confidence in them..... [redacted] age 70. Robbed of my retirement, living as a shadow -painful life. Having to beg for funding after spending retirement savings...	Thank you for your comment. The Committee very much welcomes hearing from patients and has considered your experience and views. This has contributed to their understanding of how serious the adverse events of this procedure can be. The IP Programme issues guidance on procedures after having reviewed the best existing evidence on its safety and efficacy. The Committee has considered that there is limited evidence on the efficacy and safety of laparoscopic ventral mesh rectopexy for internal rectal prolapse and has recommended special arrangements for clinical governance, patient consent (including information on types of mesh and complications) and audit or research. The Committee has also recommended that patient assessment and treatment should be done by a multidisciplinary team

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4	Consultee 4 Patient		Dear sir or madam, February 2009 I had abdominal Retropexy,anterior vaginal mesh insertion, suffered considerable pain, I knew things where not ok, went into fluid retention, ballooned up like a Michelin woman, was vomiting feacal fluid,4 days after the surgery's ,(this was joint operation I had with [redacted] and [redacted] Hospilal in Leeds)I had an emergency transfer to The Royal [redacted] Hospital where I had surgery for the mesh had eroded into my bowel,I had a temporary colostomy,I stuffed septicaemia was fed vier TPN,I continued to suffer from rectal pain,sphincter spasm and perianal discomfort,although the colostomy resolved the problem with bowel action,my consultant in Leeds told my husband and I that the only way I could have relief from rectum pain is a permanent colostomy. June that year 2009,I had operation in my local hospital in north wales by Mr [redacted],I suffered bleeding which required further surgery and a wound infection,I developed 2 small hernias.December 2015 I was refuted from my local hospital to Liverpool woman's as mesh eroded into my vagina,2.2cm was cut by Mr [redacted],since then I have suffered dreadfully with chronic pain in my lower back,where my rectum was and my sphincter,I have had spinal block in Liverpool,I was then put on a pain management-course one day a week for six weeks,put on a cocktail of medication so that I couldn't function,still going	Thank you for your comment. The Committee very much welcomes hearing from patients and has considered your experience and views. This has contributed to their understanding of how serious the adverse events of this procedure can be. The IP Programme issues guidance on procedures after having reviewed the best existing evidence on its safety and efficacy. The Committee has considered that there is limited evidence on the efficacy and safety of laparoscopic ventral mesh rectopexy for internal rectal prolapse and has

			to clinic due to vaginal,leg,back,groin,knees and feel pain,was bast on to mr [redacted] registrar for two further appointments ,asked for MRI,waited 25 weeks for results ,had translabial scan,mesh has attached itself to my coccyx and the wall of my urethra,chronic pain can't sit/stand or walk for long periods,spend most days in bed as that is the only plaice I get a bit of comfort in between tossing and turning due to hip pain,I was never told of the risks for the Retropexy or mesh,I have since found out it was Gyniecare Ethicon product that was inserted into me ,I have looked up the risks on there website and the leaflet that I wasn't given in hospital,my surgeons where very dishonest with me,they have broke every rule in the book regarding patient care,I was never told of this mesh and the Retropexy procedure had no clinical triles,this blind procedure has ruined almost 10 yrs of my life and it continues to,my husband and I have been married 40 yrs this year the last 9 yrs have been sexless ,lucky we are still together no man or woman should go through this,that's my life due to Retropexy mesh,more high risk surgery to come,can't continue living like I am,have had Two admission to mental health hospitals due to breakdown in between all this suffering.please ban this procedure and mesh.look forward to hearing from you,[redacted]	recommended special arrangements for clinical governance, patient consent (including information on types of mesh and complications) and audit or research. The Committee has also recommended that patient assessment and treatment should be done by a multidisciplinary team specialised in the management of rectal prolapse, including appropriately trained surgeons. In addition, the Committee recommended that data from patients having the procedure should be entered into the British Pelvic Floor Society database and any mesh related complications reported to the MHRA. IPAC also added a committee comment on patient experience with this procedure in section 3.8 of the guidance.
5	Consultee 5 Patient		Dear NICE Advisory Committee /Staff, I would like to make a comment based on my experience of follow up as a patient who had laparoscopic ventral mesh rectopexy in October of 2010 in [redacted].	Thank you for your comment. The Committee very much welcomes hearing from patients and has considered your experience and views. This has contributed to their understanding of how serious

			This really concerns the accuracy and quality of the initial data collected from patients such as myself during follow up after this surgery/ procedure. I feel note should be made that the quality of this data is questionable. I was given long questionnaires to complete and return at various stages during my follow up over the months and years after my surgery. As a patient I recollect I found completing the questionnaires accurately to be very difficult. This is due to the below: • As the condition is depressing, debilitating and as a patient you are desperate for improvement you try to convince yourself things are at least a little bit better and do not want to face up to the fact that they are actually worse. Hence in my case I remember scoring too optimistically especially in the first year after surgery. The questionnaires were long and tiring . • The design of the questionnaires I received did not take into account at all for new medications you may be prescribed post operatively to prevent for example constipation. Nor do the questionnaires take into account beginning the use of irrigation units upon which I was prescribed and was reliant on post the surgical procedure. How do you then accurately score changes in symptoms such as ODS or constipation, or quality of life in relation to recent surgery in a questionnaire, when you have begun to irrigate your bowels morning and evening via an irrigation unit, or if you are increasing another new medication such as a laxative? From my recollections my data could not therefore not have been accurate as I ticked the boxes as requested but remember resorting to adding additional comments alongside about new medications or use of an irrigation unit. My last point is that during follow-up clinic appointments I have attended in more recent years in Oxfordshire ,worsening symptoms especially regarding obstructive defaecation and prolonged discomfort /pain have been in my case, regarded dismissively and true outcome of the surgery has not been fully acknowledged.	the adverse events of this procedure can be. The IP Programme issues guidance on procedures after having reviewed the best existing evidence on its safety and efficacy. The Committee has considered that there is limited evidence on the efficacy and safety of laparoscopic ventral mesh rectopexy for internal rectal prolapse and has recommended special arrangements for clinical governance, patient consent (including information on types of mesh and complications) and audit or research. The Committee has also recommended that patient assessment and treatment should be done by a multidisciplinary team specialised in the management of rectal prolapse, including appropriately trained surgeons. In addition, the Committee recommended that data from patients having the procedure should be entered into the British Pelvic Floor Society database and any mesh related complications reported to the MHRA.

			I hope some of this may help inform during the consultation. Although in my particular case surgery was treating external prolapse additionally to rectocele and ODS, and I know is not the remit for the current consultation, I still feel the above points to be relevant. [redacted]	IPAC also added a committee comment on patient experience with this procedure in section 3.8 of the guidance.
6	Consultee 6 Patient		To whom it may concern, This was brought to my attention tonight March 22nd after the 5pm deadline to submit comments to be consider during the review of LVMR. I thought I would go ahead and put forward my experience and comments anyway in the hope they can be added to the information you are gathering. Wether you include them or not is up to you. I had an attempted LVMR in October 2011, my surgeon was Mr [redacted] at The [redacted]. He abandoned the attempt when he discovered he did not have enough theatre time left and I had a pelvis obliterated with adhesions. He brought me back the following year June 2012 and did an abdominal mesh rectopexy. I have struggled from the moment I had the surgery, in pain and still had the same symptoms that would gradually worsen. I am six years post op do not work, unable to care for my family and have very poor quality of life. My bowel does not function at all, I have developed fibromyalgia and random histamine outbreaks of hives. I have pudendal nerve pain, vulvodynia and back pain in addition to fibromyalgia. I strongly feel the mesh has not only failed in it's purpose and it is now causing untold damage and complications for me. Mr [redacted] was not	Thank you for your comment. The Committee very much welcomes hearing from patients and has considered your experience and views. This has contributed to their understanding of how serious the adverse events of this procedure can be. The IP Programme issues guidance on procedures after having reviewed the best existing evidence on its safety and efficacy. The Committee has considered that there is limited evidence on the efficacy and safety of laparoscopic ventral mesh rectopexy for internal rectal prolapse and has recommended special arrangements for clinical governance, patient consent (including information on types of mesh and complications) and audit or research.

			interested post op and just prescribed an irrigation kit and referred me to his nurse. I have not been able to use the kit as a way of management as it caused too much pain. I have up to now found my own ways to cope which are not very dignified. I do not know what the mesh is doing to my internal organs but I am at the beginning of trying to find out. My GP has referred me to Miss [redacted] this week for which I will have a long wait but I hope I can have the mesh removed and the complications investigated instead of having to live with them. Mesh should be banned outright or at least suspended until all patients like myself have been investigated. For your guidline review I would like you to consider heavily if patients are good candidates to begin with. I had a pelvis full of adhesions but he still went ahead. After care has to be better quality, patients should not be left feeling that the mesh failing to improve their symptoms is their fault. I felt this! If irrigation was offered so readily at my one and only follow up appointment why was this not an option offered before surgery. There was no options other than surgery offered in the first instance. Patients should be informed of the dangers of mesh, how it can behave once implanted, how it can break up, migrate elsewhere and how it can erode into other organs and through tissues, how it can wrap around structures and organs. I was told nothing apart from a fleeting comment that your husband my feel a difference during intercourse. I questioned that comment and was told the back wall of your vagina will feel a bit thicker to him but I myself wouldn't notice a difference. For the record I cannot have an intimate relationship with my husband the pain I am in prevents it. Patients should be warned their physical relationships might be scacrificed on a gamble that mesh will improve their bowel function.	The Committee has also recommended that patient assessment and treatment should be done by a multidisciplinary team specialised in the management of rectal prolapse, including appropriately trained surgeons. In addition, the Committee recommended that data from patients having the procedure should be entered into the British Pelvic Floor Society database and any mesh related complications reported to the MHRA. IPAC also added a committee comment on patient experience with this procedure in section 3.8 of the guidance.

			A national register should be set up to question all former Rectopexy patients and this procedure halted until factual accounts of their post operative outcomes are recorded and reviewed. There must be hundreds if not thousands who are yet to catch up with social media and the mesh crisis like myself who have only just found the support groups. The NHS owe it to them to recall all female & male patients to ask what their individual situations are presently so many years down the line after rectopexy mesh. I believe this is the only accurate way to fully assess and review if it is right to continue to offer mesh to patients. This needs to be done so true statistics of favourable outcomes can be offered to future patients so they can be fully informed and assess the risks themselves before consenting. It is impossible for you to have those factual percentages as nobody is bothering to ask former patients. I hope you take into account my email. Regards	

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