NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to: Sally.Jones@nice.or.uk or Hawra.Abugulal@nice.org.uk

Procedure Name:	Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) for treating severe obesity (IP1340)
Name of Specialist Advisor:	Mr Kesava Reddy Mannur
Specialist Society:	Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland

1 Do you have adequate knowledge of this procedure to provide advice?

☒ Yes.

☐ No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

☒ Yes.

☐ No. If no, please enter any other titles below.

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

☒ Yes.

☐ Is there any kind of inter-specialty controversy over the procedure?

☐ No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

This procedure has been done for more than 9 years now across the world mostly in Spain and to an extent in Germany. It is also being performed in USA, Turkey and many more countries. This has been published over a period of time in the reputed journals – Obesity surgery

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

☐ I have never done this procedure.

☒ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

This surgery is derived from Duodenal Switch, which I do regularly. I have performed this surgery in a few cases as the Duodenal Switch could not be completed because of the difficulty in completing the second part of the Duodenal Switch – Ileo-ileal anastomosis. This is similar to minigastric bypass and Roux-en-Y gastric bypass, but in SADI-S there is no bile reflux into the stomach as the anastomosis is beyond (distal to) the pylorus. I have done 2 patients for SADI- S only as the results have been similar to DS with less time to perform the procedure; it is gradually felt the RNY part of the DS is not necessary because of the intact pylorus.

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

☐ I have never taken part in the selection or referral of a patient for this procedure.

☐ I have taken part in patient selection or referred a patient for this procedure at least once.

☒ I take part in patient selection or refer patients for this procedure regularly.

Comments:

It has the same indications of DS; it is used in super obese patients or in patients with severe metabolic problems eg. Diabetes

2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

☒ I have done bibliographic research on this procedure.

☐ I have done research on this procedure in laboratory settings (e.g. device-related research).

☐ I have done clinical research on this procedure involving patients or healthy volunteers.

☐ I have had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

There is a reasonable amount of information on this procedure with regard to various fields post-bariatric surgery – weight loss, diarrhoea, diabetes and hypertension resolution, HbA1c, C peptide, HOMA IR etc.
Here are some of the publications I used. I know Antonio Torres work very well in the conferences and symposiums. The recent update he gave was in December 2015 in Keel symposium in Stoke–on-Trent.

A. Proximal Duodenal–Ileal End-to-Side Bypass with Sleeve Gastrectomy: Proposed Technique
Andrés Sánchez-Pernaute & Miguel Angel Rubio Herrera &
Elia Pérez-Aguirre & Juan Carlos García Pérez &
Lucio Cabrerizo & Luis Díez Valladares & Cristina Fernández &
Pablo Talavera & Antonio Torres
Published online: 27 November 2007
Springer Science + Business Media B.V. 2007
- OBES SURG (2007) 17:1614–1618 DOI 10.1007/s11695-007-9287-8

B. Single-anastomosis duodenoileal bypass with sleeve gastrectomy: metabolic improvement and weight loss in first 100 patients
Andrés Sánchez-Pernaute, M.D., Ph.D.a,*, Miguel Ángel Rubio, M.D., Ph.D.b,
Elia Pérez Aguirre, M.D., Ph.D.a, Ana Barabash, M.D., Ph.D.b,
Lucio Cabrerizo, M.D., Ph.D.b, Antonio Torres, M.D., Ph.D.a
aDepartment of Surgery, Hospital Clínico San Carlos, Madrid, Spain
bDepartment of Endocrinology, Hospital Clínico San Carlos, Madrid, Spain
Received March 10, 2012; accepted July 28, 2012
- Surgery for Obesity and Related Diseases 9 (2013) 731–735

C. Single Anastomosis Duodeno–Ileal Bypass with Sleeve Gastrectomy (SADI-S). One to Three-Year Follow-up
Andrés Sánchez-Pernaute & Miguel Angel Rubio Herrera & María Elia Pérez-Aguirre &
Pablo Talavera & Lucio Cabrerizo & Pilar Matía & Luis Díez-Valladares &
Ana Barabash & Estaban Martín-Antona & Alejandra García-Botella &
Ester Martín Garcia-Almenta & Antonio Torres
- OBES SURG : DOI 10.1007/s11695-010-0247-3

D. Single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) for obese diabetic patients
Andrés Sánchez-Pernaute, M.D., Ph.D.a,*, Miguel Ángel Rubio, M.D., Ph.D.b,
Lucio Cabrerizo, M.D., Ph.D.b, Ana Ramos-Levi, M.D., Ph.D.c,
Elia Pérez-Aguirre, M.D., Ph.D.a, Antonio Torres, M.D., Ph.D.a
aDepartment of Surgery, Hospital Clínico San Carlos, Madrid, Spain
bDepartment of Endocrinology, Hospital Clínico San Carlos, Madrid, Spain
cDepartment of Endocrinology, Hospital "La Princesa," Madrid, Spain
Received October 25, 2014; accepted January 29, 2015
- Surgery for Obesity and Related Diseases 11 (2015) 1092–1098

E . Pylorus preserving loop duodeno-enterostomy with sleeve gastrectomy - preliminary results
Jodok Matthias Grueneberger1*, Iwona Karcz-Socha2, Goran Marjanovic1, Simon Kuesters1,
Krystyna Zwirska-Korczala2, Katharina Schmidt3 and W Konrad Karcz3
Grueneberger et al. BMC Surgery 2014, 14:20
http://www.biomedcentral.com/1471-2482/14/20

F. Robotically Assisted Single Anastomosis Duodenoileal Bypass
after Previous Sleeve Gastrectomy Implementing High Valuable
Technology for Complex Procedures
Ramon Vilallonga,1 JoséManuel Fort,1 Enric Caubet,1 Oscar Gonzalez,1
JoséMaria Balibrea,1 Andrea Ciudin,2 andManel Armengol1
1Endocrine, Metabolic and Bariatric Unit, General Surgery Department, Vall d'Hebron University Hospital,
Center of Excellence for the EAC-BC, Passeig de la Vall d'Hebron 119-129, 08035 Barcelona, Spain
2Endocrinology Department, Vall d'Hebron University Hospital,
- Journal of Obesity
Volume 2015, Article ID 586419, 6 pages
http://dx.doi.org/10.1155/2015/586419

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

☒ Established practice and no longer new.

☒ A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

☐ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

SADI-S is done exactly like DS up to the point of the Duodeno-ileal anastomosis. Only thing is the next part of the operation – dividing the Biliary limb (ileum) is not disconnected and then anastomosed to the Alimenetary limb (Ileum) – ileo-ileal anastomosis. This is mainly to prevent the biliary reflux. This is not a problem in SADI-S as in Mini-gastric bypass, as the SADI-S has the intact pylorus and the duodenum is a natural environment for the bile (unlike the stomach pouch in Minigastric bypass). Duodenal Switch is considered slightly difficult technically and takes more time. SADI-S takes about 30minutes less time to perform. Also if the bile reflux into the stomach is a problem (if the pylorus is not working well), then it is very easy to add RNY part of ileo-ileal anastomosis very easily. Also there are no reported internal hernias at mesenteric defect with SADI-S procedure.

3.2 What would be the comparator (standard practice) to this procedure?

DUODENAL SWITCH AND TO AN EXTENT DISTAL GASTRIC BYPASS

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

☒ Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Adverse events reported in the literature (if possible please cite literature)

a. As in every bariatric procedure- gastric bypass or DS, Main problem with SADI-S is anastomotic leak at Duodeno-ileal anastomosis, It is not more than 1.3% which is similar to DS and probably slightly more than Gastric bypass. With experience, this should come down as it happened with Gastric bypass or DS.

b. increased frequency of bowel movements- 2.1 times. A couple of patients have about 3 times. It is similar or less than DS. Bowel frequency will reduce with the dietary modification. If it is still a problem, the Alimentary length can be increased or converted to DS by surgery.

c. protein malnutrition- it is slightly less than after DS. If it is a problem then the absorptive area could be increased by increasing the alimentary limb or converting into DS with increased alimentary limb and common limb. It happened in 4 out of 100 patients in one study; it happened in wrong type of patients who would not have understood the dietary requirements. The case selection could have been refined and already these have been put into practice.

d. vitamin and mineral deficiencies – these happen almost similar to gastric bypass and less than in DS. These could be prevented by taking the extra vitamin and mineral supplements. These can happen in

2. Anecdotal adverse events (known from experience)

3. Theoretical adverse events

4.2 What are the key efficacy outcomes for this procedure?

Weight loss, remission of diabetes, OSA and Hypertension.

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

No.

4.4 What training and facilities are needed to do this procedure safely?

All bariatric surgeons who can do DS can do this. All other bariatric surgeons should get training from those who are doing DS or SADI-S.

4.5 Are there any major trials or registries of this procedure currently in progress? If so, please list.

There are no trials but there are registries of this procedure in Madrid and Barcelona.

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

No.

5 Audit Criteria
Please suggest a minimum dataset of criteria by which this procedure could be audited.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures):

Percent excess weight loss and BMI lowering, resolution of Diabetes (HbA1C >6), hypertension and Obstructive Sleep apnoea,

5.2 Adverse outcomes (including potential early and late complications):

anastomotic leak, bleeding, intra-abdominal abscesses and other infections, death, hypoalbuminaemia, Vitamin A, D and other vitamin Deficiencies, Selenium, copper and Zinc deficiencies, weight regain

6 Trajectory of the procedure

6.1 In your opinion, how quickly do you think use of this procedure will spread?

Within a year, but still it wont be done by a few handful of surgeons in this country and it wont be more than 10% of all procedures

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

☐ Most or all district general hospitals.

☐ A minority of hospitals, but at least 10 in the UK.

☒ Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

☐ Major.

☐ Moderate.

☒ Minor.

Comments:
This will not increase the number of bariatric surgeries performed in this country. But instead of some other operations like gastric bypass or mini-gastric bypass, this will be done. Or instead of DS, this may be performed. It will only complement the surgical procedures available to the surgeons but doesn't increase the total number of surgeries done in the country.

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

8 Data protection and conflicts of interest

8. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The specialist advice questionnaire will be published in accordance with our guidance development processes and a copy will

be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

X

I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above and in accordance with the Data Protection Act 1998.

8.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy ~~(attached)~~ as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional payments in cash or kind	☐	**YES**
	☒	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	☐	**YES**
	☒	**NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐	**YES**
	☒	**NO**
Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	☐	**YES**
	☒	**NO**
Investments – any funds that include investments in the healthcare industry	☐	**YES**
	☒	**NO**

[1] 'Family members' refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	☐	**YES**
	☒	**NO**

Do you have a **non-personal** interest? The main examples are as follows:

Fellowships endowed by the healthcare industry	☐	**YES**
	☒	**NO**
Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts	☐	**YES**
	☒	**NO**

If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

Comments:

Thank you very much for your help.

Professor Bruce Campbell, Chairman, Interventional Procedures Advisory Committee

Professor Carole Longson, Director, Centre for Health Technology Evaluation.

April 2014

Conflicts of Interest for Specialist Advisers

1 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.

1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

2 Personal pecuniary interests

2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as **'specific'** or to the industry or sector from which the product or service comes, in which case it is regarded as **'non-specific'**. The main examples are as follows.

2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.2 **Fee-paid work** – any work commissioned by the healthcare industry for which the member is paid in cash or in kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

2.1.3 **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.

2.1.4 **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place.

2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

2.2 No personal interest exists in the case of:

2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

2.2.2 accrued pension rights from earlier employment in the healthcare industry.

3 **Personal family interest**

3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.

3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.

3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.

3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).

3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)

3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

3.2 No personal family interest exists in the case of:

3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

3.2.2 accrued pension rights from earlier employment in the healthcare industry.

4 **Personal non-pecuniary interests**

These might include, but are not limited to:

4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review

4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence

4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration

4.4 other reputational risks in relation to an intervention under review.

5 Non-personal interests

5.1 A non-personal interest involves payment that benefits a department or organisation for which a Specialist Advisor is responsible, but that is not received by the Specialist Advisor personally. This may either relate to the product or service being evaluated, in which case it is regarded as **'specific,'** or to the manufacturer or owner of the product or service, but is unrelated to the matter under consideration, in which case it is regarded as **'non-specific'**. The main examples are as follows.

5.1.1 **Fellowships** – the holding of a fellowship endowed by the healthcare industry.

5.1.2 **Support by the healthcare industry or NICE** – any payment, or other support by the healthcare industry or by NICE that does not convey any pecuniary or material benefit to a member personally but that does benefit his/her position or department. For example:

- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Adviser is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to: Sally.Jones@nice.or.uk or Hawra.Abugulal@nice.org.uk

Procedure Name:	Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) for treating severe obesity (IP1340)
Name of Specialist Advisor:	Mr Marco Adamo
Specialist Society:	Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland

1 Do you have adequate knowledge of this procedure to provide advice?

☒ Yes.

☐ No – please return the form/answer no more questions.

1.1 Does the title used above describe the procedure adequately?

☒ Yes.

☐ No. If no, please enter any other titles below.

Comments:

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

☒ Yes.

☐ Is there any kind of inter-specialty controversy over the procedure?

☒ No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

Comments:

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

☒ I have never done this procedure.

☐ I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

☐ I have never taken part in the selection or referral of a patient for this procedure.

☒ I have taken part in patient selection or referred a patient for this procedure at least once.

☐ I take part in patient selection or refer patients for this procedure regularly.

Comments:

2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

☒ I have done bibliographic research on this procedure.

☐ I have done research on this procedure in laboratory settings (e.g. device-related research).

☐ I have done clinical research on this procedure involving patients or healthy volunteers.

☐ I have had no involvement in research on this procedure.

☒ Other (please comment)

Comments: I have visited University Hospital in Spain where procedure has been designed and carried out for several years. Procedure has been approved in my NHS hospital (University College London) and we are in the process of starting a RCT

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

☐ Established practice and no longer new.

☒ A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

☐ Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:
It is an established procedure abroad, not yet performed in UK. There are no concerns worldwide on its efficacy and safety. 5 Years date have been published.

3.2 What would be the comparator (standard practice) to this procedure?

Roux en Y Gastric Bypass. Duodenal Switch

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☒ 10% to 50% of specialists engaged in this area of work.

☐ Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:
No one in UK

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Adverse events reported in the literature (if possible please cite literature)

   Standard postoperative complication rates common to any bariatric procedure such as bleeding, infection, anastomotic leak

2. Anecdotal adverse events (known from experience)

   Don't know any

3. Theoretical adverse events

   Malabsorption and vitamin and mineral deficiencies if patient not compliant with medical recommendations

4.2 What are the key efficacy outcomes for this procedure?

Weight loss and health improvement. Type 2 diabetes remission or amelioration. Resolution of obesity related comorbidities

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

Malnutrition and vitamin/ mineral deficiencies in non compliant patients

4.4 What training and facilities are needed to do this procedure safely?

Skills and facilities are mostly transferable from the bariatric procedures currently performed (sleeve Gastrectomy and gastric bypass). Specific operating technical details can be easily learnt by observing the procedure being done.

4.5 Are there any major trials or registries of this procedure currently in progress? If so, please list.

Procedures are being recorded in the Spanish Bariatric Surgery Registry. Multicentre RCT between SADI-S and Duodenal Switch currently ongoing in Spain.

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes, please list.

Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please

do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

Several published paper are available. Data are currently been presented during most international bariatric surgical meeting.

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

I am not aware of any controversy around the procedure which can be defined as a technical variation of several existing procedures.

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.

Same dataset currently used for all other bariatric procedures currently performed in UK. Procedures should also be recorded in the National Bariatric Surgery Registry

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures):

Same outcome measures currently in place for the other bariatric procedures

5.2 Adverse outcomes (including potential early and late complications):

Same outcome measures currently in place for the other bariatric procedures for both short and long term outcomes

6 Trajectory of the procedure

6.1 In your opinion, how quickly do you think use of this procedure will spread?

The procedure will grow very quickly, initially as revision procedure for failed Sleeve Gastrectomy (which is part of the SADI-S)

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

☐ Most or all district general hospitals.

☐ A minority of hospitals, but at least 10 in the UK.

☐ Fewer than 10 specialist centres in the UK.

☒ Cannot predict at present.

Comments:

Most of the main teaching hospital with established bariatric unit will consider undertake the procedure as either primary or revisional surgery

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

☐ Major.

☐ Moderate.

☒ Minor.

Comments:
Procedure is cost comparable (if not cheaper) with existing procedures. It will be used as an alternative to existing procedures for patients already eligible for bariatric surgery as per NICE guidelines.

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

Procedure is currently being performed in most European and Western Countries with outcomes published.

8 Data protection and conflicts of interest

8. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The specialist advice questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

☐ I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above and in accordance with the Data Protection Act 1998.

8.2 **Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee**

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy ~~(attached)~~ as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures.

Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

Consultancies or directorships attracting regular or occasional payments in cash or kind	☐	**YES**
	☒	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	☒	**YES**
	☐	**NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐	**YES**
	☒	**NO**
Expenses and hospitality – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences	☐	**YES**
	☒	**NO**
Investments – any funds that include investments in the healthcare industry	☐	**YES**
	☒	**NO**
Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?	☐	**YES**
	☒	**NO**

Do you have a **non-personal** interest? The main examples are as follows:

Fellowships endowed by the healthcare industry	☒	**YES**
	☐	**NO**
Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts	☒	**YES**
	☐	**NO**

If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

Comments:

Consultant for healthcare industry companies (GORE, Ethicon Endosurgery) with regards to surgical training and proctorship.

[1] 'Family members' refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

I have been programme director of an industry funded Fellowhip in Bariatric Surgery (Recognised by the Royal College of Surgery) for the past 5 years. Fellowship was funded by unconditional educational grant.

Thank you very much for your help.

Professor Bruce Campbell, Chairman, Interventional Procedures Advisory Committee

Professor Carole Longson, Director, Centre for Health Technology Evaluation.

April 2014

Conflicts of Interest for Specialist Advisers

1 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.

1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

2 Personal pecuniary interests

2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as **'specific'** or to the industry or sector from which the product or service comes, in which case it is regarded as **'non-specific'**. The main examples are as follows.

2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).

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2.2 No personal interest exists in the case of:

2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

2.2.2 accrued pension rights from earlier employment in the healthcare industry.

3 **Personal family interest**

3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.

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These might include, but are not limited to:

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- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Adviser is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers. Certain conflicts exclude you from offering advice, however, please return the questionnaire to us incomplete for our records.

Please respond in the boxes provided.

Please complete and return to: Sally.Jones@nice.or.uk or Hawra.Abugulal@nice.org.uk

Procedure Name:	Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) for treating severe obesity (IP1340)
Name of Specialist Advisor:	Mr James Byrne
Specialist Society:	Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland

1 Do you have adequate knowledge of this procedure to provide advice?

Yes.

1.1 Does the title used above describe the procedure adequately?

Yes.

2 Your involvement in the procedure

2.1 Is this procedure relevant to your specialty?

Yes.

Comments:

The next 2 questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure, please answer question 2.2.2.

2.2.1 If you are in a specialty that does this procedure, please indicate your experience with it:

I have never done this procedure.

2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

I have never taken part in the selection or referral of a patient for this procedure.

2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

Other (please comment)

Comments:

I am a council member of BOMSS(British Obesity and Metabolic Surgery Society) and have discussed this procedure with colleagues within the society. I have also performed a limited bibliographic review of this procedure.

3 Status of the procedure

3.1 Which of the following best describes the procedure (choose one):

NO Established practice and no longer new.

PARTLY A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

PARTLY Definitely novel and of uncertain safety and efficacy.

NO The first in a new class of procedure.

Comments:

The procedure works on similar principle to the duodenal switch(DS). This is a well established but relatively uncommonly performed procedure in UK bariatric surgical practice. Whilst it is recognised to be highly effective in terms of achieving weight loss and co-morbidity (particularly type 2 diabetes) DS is perceived by most as relatively high risk both peri and post operatively. The per-operative risk relates in large part to complications related to the duodenal anastomosis, and the long term risk is one of nutritional failure/deficiency.

SADI can be performed either as:

i) Primary procedure, i.e. performing the sleeve at the same time as the anastomosis between the duodenum and small bowel

ii) Secondary/staged procedure. This is where the intention has always been to perform the intervention, but the sleeve gastrectomy is preformed first and the duodeno-intestinal anastomosis is performed as a planned secondary procedure 6-12 months after the initial operation
iii) Revisional procedure. This is where the operation is performed for either primary failure or secondary failure/weight regain following a sleeve gastrectomy

3.2 What would be the comparator (standard practice) to this procedure?

Duodenal Switch, Gastric bypass, 'Mini' or Omega loop bypass

3.3 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

NO More than 50% of specialists engaged in this area of work.

NO 10% to 50% of specialists engaged in this area of work.

YES Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

I am aware of a small number of surgeons in the UK performing this procedure at present. I understand that those performing SADI-S have performed small numbers of procedures (all<10 each).

4 Safety and efficacy

4.1 What is the potential harm of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

1. Adverse events reported in the literature (if possible please cite literature)

i. Standard per-operative risks for bariatric surgery

ii. Leakage form the duodeno-intestinal anastomosis

iii. Pancreatic leak/injury

iv. Malnutrition/nutritional failure if the common channel (the part of the intestine downstream of the duodeno-intestinal anastomosis) is too short

2. Anecdotal adverse events (known from experience)

NIL

3. Theoretical adverse events

See above

4.2 What are the key efficacy outcomes for this procedure?

Weight loss
Improvement in co-morbidities related to obesity
Overall quality of life
Nutrient and micronutrient deficiencies

4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?

Weight loss
Improvement in co-morbidities related to obesity
Overall quality of life
Nutrient and micronutrient deficiencies

4.4 What training and facilities are needed to do this procedure safely?

i. Advanced laparoscopic skills as pre standard bariatric surgical practice
ii. Experience and skill in mobilising duodenum form head of pancreas. This is not within routine scope of practice of surgeons engaged in standard UK bariatric surgical practice. This is within the standard scope of practice of surgeons performing laparoscopic gastric resection(typically in cancer practice). The small minority of UK bariatric surgeons with skill and expertise in performing duodenal switch procedures have the appropriate technical expertise and skills to perform this procedure.
iii. Experience and skill in performing duodenointestinal anastomosis safely. This is a relatively 'high risk' anastomosis because of the duodenal vascularity and possibility of minor pancreatic injury during dissection that may be a subsequent risk factor for leakage from this join in the bowel – most surgeons regard the duodenum as a much less 'forgiving' organ than the stomach for anastomosis/bowel joins. The small minority of UK bariatric surgeons with skill and expertise in performing duodenal switch procedures have the appropriate technical expertise and skills to perform this procedure.

4.5 Are there any major trials or registries of this procedure currently in progress? If so, please list.

There is an ongoing study of this procedure on clinical trials.gov that has been recruiting for some years in Spain; according to the website this study is not yet complete. This procedure is not captured within the UK national bariatric surgery registry

4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, for example PUBMED? (This can include your own work). If yes,

please list.
Please note that NICE will do a literature search: we are only asking you for any very recent or potentially obscure abstracts and papers. Please do not feel the need to supply a comprehensive reference list (but you may list any that you think are particularly important if you wish).

NO

4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

Obtaining informed Consent from patients for a procedure where the peri-operative risks are not clearly defined, together with the long term outcome/risks of this procedure, specifically nutritional deficiency/failure.

5 Audit Criteria

Please suggest a minimum dataset of criteria by which this procedure could be audited.

5.1 Outcome measures of benefit (including commonly used clinical outcomes, both short and long - term; and quality-of-life measures):

Weight loss
Improvement/remission of comorbidity
Quality of life using appropriately validated instruments

5.2 Adverse outcomes (including potential early and late complications):

Early
Standard adverse bariatric outcome measures
Anastomosis problems - bleed, leak
pancreatic injury/fistula

Late
Standard adverse bariatric outcome measures
Specific focus in nutritional problems/deficiency

6 Trajectory of the procedure

6.1 In your opinion, how quickly do you think use of this procedure will spread?

Public sector – Slow initially. If found to be safe and effective then it may develop a place in the management of patients with either primary or secondary failure of a sleeve gastrectomy.

Private sector. Spread/uptake may is likely to be slow in private sector although individual(s) may have a strong belief in the safety and efficacy of this procedure and wish to offer it in the self pay market.

6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):

NO Most or all district general hospitals.

YES A minority of hospitals, but at least 10 in the UK.

NO Fewer than 10 specialist centres in the UK.

NO Cannot predict at present.

Comments:

Uptake should be determined in light of evidence of safety and effectiveness. As a revision procedure for sleeve gastrectomy, an increasingly popular option for patients having bariatric surgery, it may become part of the armamentarium of revisional weight loss surgery in the UK

6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:

NO Major.

NO Moderate.

YES Minor.

Comments:
If utilised as revision for failure after sleeve gastrectomy rather than primary procedure

7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

This is a procedure that may give rise to good weight loss and overall quality of life in appropriately selected patients. The safety and efficacy profile is not well described outside of single centre studies that are prone to bias and under-reporting of complications.
I am concerned regarding both procedure safety and long term outcomes. For this reason in my view the procedure should at present only be offered in the context of insititutionally and ethically approved study, until safety, effectiveness and training needs for the procedure can be clearly defined.
There is currently no means of capturing outcomes for patients having this procedure in the UK. An obvious way of capturing basic outcome and safety data would be to create the appropriate data pages/data fields within the National Baritrtic Surgery Rgeistry, where all NHS bariatric procedures are mandated to be entered, and shortly all privately performed procedures will also be entered

8 Data protection and conflicts of interest

8. Data protection, freedom of information and conflicts of interest

8.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The specialist advice questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

YES I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above and in accordance with the Data Protection Act 1998.

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Consultancies or directorships attracting regular or occasional payments in cash or kind	☐	
	☐	**NO**
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	☐	
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Investments – any funds that include investments in the healthcare industry ☐

☐ **NO**

Do you have a **personal non-pecuniary** interest – for example have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic? ☐

☐ **NO**

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☐ **NO**

Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts ☐

☐ **NO**

If you have answered YES to any of the above statements, please describe the nature of the conflict(s) below.

Comments:
I am engaged in private practice as a consultant surgeon. Part of my private practice is bariatric surgery.

Thank you very much for your help.

Professor Bruce Campbell, Chairman, Interventional Procedures Advisory Committee

Professor Carole Longson, Director, Centre for Health Technology Evaluation.

April 2014

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