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38) NICE interventional procedure guidance [IPG331]-1

Published date: February 2010: http://www.nice.org.uk/guidance/IPG331

Cytoreduction surgery followed by hyperthermic intraoperative peritoneal chemotherapy for peritoneal carcinomatosis **NICE interventional procedure guidance [IPG331]** Published date: February 2010

Register an interest in this interventional procedure

·Colorectal cancer

•Next

The National Institute for Health and Clinical Excellence (NICE) has issued full guidance to the NHS in England, Wales, Scotland and Northern Ireland on Cytoreduction surgery followed by hyperthermic intraoperative peritoneal chemotherapy for peritoneal carcinomatosis.

It replaces the previous guidance on Cytoreduction surgery followed by hyperthermic intraoperative peritoneal chemotherapy for peritoneal carcinomatosis (Interventional Procedures Guidance no. 116, November 2004).

Description

Peritoneal metastases commonly result from the regional spread of gastrointestinal, gynaecological and other malignancies. Peritoneal carcinomatosis is an advanced form of cancer associated with short survival and poor quality of life, which may lead to bowel obstruction, ascites and pain.

This procedure was developed by Paul Sugarbaker at the Washington Cancer Institute. A laparotomy is performed under general anaesthesia and all gross tumour is removed along with the involved organs, peritoneum and tissue. The surgery includes:

- •removal of the right hemicolon, spleen, gall bladder, parts of the stomach, greater omentum and lesser omentum
- •stripping of the peritoneum from the pelvis and diaphragm
- •stripping of tumour from the surface of the liver
- •removal of the uterus and ovaries in women
- •removal of the rectum in some cases.

The aim of the surgery is to remove all macroscopic tumour, although residual tumour is sometimes left behind. In the second stage of the procedure, the abdomen is perfused with fluid containing a chemotherapy agent, heated to between 40 and 48° C. The fluid is perfused for 60 to 120 minutes and then drained from the abdomen, before the laparotomy is closed. A

further course of systemic or intraperitoneal chemotherapy may be administered after the surgery.

Intraoperative intraperitoneal administration of chemotherapy allows the drug to be distributed uniformly to all surfaces of the abdomen and pelvis. Potential advantages of heating the perfusion fluid are that it increases drug penetration and the cytotoxic effect of drugs such as mitomycin C and cisplatin.

•OPCS4.6 Code(s)

This procedure cannot be expressed in the OPCS-4 classification by a single code. The current guidance would be to code each organ removed as per normal coding rules, and to combine this with the ICD-10 diagnosis code *C78.6 Secondary malignant neoplasm of retroperitoneum and peritoneum*. The appropriate code for the primary malignant neoplasm is also recorded, if this is not stated or unspecified then a code from category *C80.- Malignant neoplasm, without specification of site* is recorded. Heated chemotherapy cannot currently be specifically captured using OPCS-4. At present this is captured using the following codes:

T48.2 Introduction of cytotoxic substance into peritoneal cavity plus a code from categories X70-X71 Procurement of drugs for chemotherapy for neoplasm in Bands 1-10 dependent on the regimen prescribed.

The NHS Classifications Service of NHS Connecting for Health is the central definitive source for clinical coding guidance and determines the coding standards associated with the classifications (OPCS-4 and ICD-10) to be used across the NHS. The NHS Classifications Service and NICE work collaboratively to ensure the most appropriate classification codes are provided. www.connectingforhealth.co.uk/clinicalcoding

38) NICE interventional procedure guidance [IPG331]-2

1 Guidance

1 Guida nce

- 1.1 Current evidence on the efficacy of cytoreduction surgery (CRS) followed by hyperthermic intraoperative peritoneal chemotherapy (HIPEC) for peritoneal carcinomatosis shows some improvement in survival for selected patients with colorectal metastases, but evidence is limited for other types of cancer. The evidence on safety shows significant risks of morbidity and mortality which need to be balanced against the perceived benefit for each patient. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake CRS followed by HIPEC for peritoneal carcinomatosis should take the following actions.
- •Inform the clinical governance leads in their Trusts.
- •Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy in relation to the potential morbidity and mortality and the prolonged recovery period, and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended.
- •Audit and review clinical outcomes of all patients having CRS followed by HIPEC for peritoneal carcinomatosis (see section 3.1).
- 1.3 Patient selection and treatment should be carried out in the context of a multidisciplinary team, including oncologists and surgeons with experience in this operation.
- 1.4 NICE encourages further research into this procedure which should take the form of randomised controlled trials (RCTs) with clear descriptions of patient selection criteria and the types of cancer being treated. The chemotherapy regimens used should be well defined. Outcome measures should include survival and quality of life.

2 The procedure

- 2.1 Indications and current treatments
- 2.2 Outline of the procedure
- 2.3 Efficacy
- 2.4 Safety

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Peritoneal carcinomatosis is advanced cancer associated with short survival and poor quality of life.
- 2.1.2 Current treatments include systemic chemotherapy with the aim of prolonging survival, and/or surgery for short-term palliation of complications such as bowel obstruction.

2.2 Outline of the procedure

- 2.2.1 Cytoreduction surgery aims to remove all macroscopic tumours. Intraoperative intraperitoneal administration of chemotherapy aims to distribute the drug uniformly to all surfaces of the abdomen and pelvis.
- 2.2.2 With the patient under general anaesthesia, appropriate CRS is carried out, followed by perfusion of the abdomen with heated chemotherapy solution (heating increases penetration and cytotoxic effects). The abdomen is drained prior to closure. A further course of systemic or early postoperative intraperitoneal chemotherapy (EPIC) may be administered.

2.3 Efficacy

- 2.3.1 A systematic review of 4500 patients with peritoneal carcinomatosis of colorectal origin reported an overall median 5-year survival of 19% (16 studies).
- 2.3.2 A non-randomised comparative study of 506 patients with peritoneal carcinomatosis of colorectal origin comparing CRS and HIPEC (271 patients) with CRS and EPIC (123 patients) and CRS and HIPEC plus EPIC (112 patients) reported no significant difference in median survival between the groups (19.2 months, 19.2 months and 21.6 months respectively) (p = 0.61).
- 2.3.3 A case series of 96 patients with peritoneal carcinomatosis of varying primary tumour origin treated by CRS and HIPEC reported a significant improvement in quality of life (using the Short Form-36 questionnaire), with an increase in mean score from 69.5 to 80 at 6-month follow-up (significance not stated).
- 2.3.4 The Specialist Advisers listed key efficacy outcomes as survival, quality of life, symptom palliation, recurrence rate and return to work and recreational activities.

2.4 Safety

- 2.4.1 A meta-analysis of 4 comparative studies included in the systematic review of 4500 patients reported a 3-year survival hazard ratio of 0.55 (95% confidence interval: 0.4–0.75), indicating that patients were more likely to survive if they received CRS plus HIPEC or EPIC (total number of patients not stated).
- 2.4.2 The systematic review of 4500 patients reported a mortality range of 0-12% (27 studies) (follow-up not stated). A postoperative mortality rate of 4% (20/506) was reported in the non-randomised comparative study of 506 patients. Deaths were attributed to the following causes: septic shock (9), respiratory complications (5), pulmonary embolus (1), stroke (1), peritonitis (1), acute renal failure (1), aplasia (not otherwise described) (1) and unknown causes (1) (timing of events not stated). In an RCT of 105 patients (CRS, HIPEC and systemic chemotherapy group), 3 patients died from abdominal sepsis (2 within 40 days, 1 more than 3 months after the procedure) and 1 patient died of pulmonary embolism more than 3 months after the procedure.
- 2.4.3 Myocardial necrosis and myocardial infarction were reported in 1 patient each in case series of 207 and 122 patients (varying tumour origin; timing of events not stated).
- 2.4.4 Acute renal failure was reported in 3% (2/59) (successfully treated by medical therapy) and 1% (1/140) (requiring dialysis in intensive care) of patients in case series of 59 and 140 patients respectively (varying tumour origin). Haemolytic-uraemic syndrome occurred in 1 patient in the case series of 122 patients.
- 2.4.5 The Specialist Advisers listed possible adverse events as bowel obstruction, bleeding, abdominal pain, eating disturbances, vascular, ureteric and bile duct injury, liver dysfunction and failure, neuropathy and anaphylaxis.

38) NICE interventional procedure guidance [IPG331]-3

3 Further information

Information for patients

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and developed <u>audit support</u> (which is for use at local discretion).

3.2 For related NICE guidance see our website.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 About this guidance

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

It updates and replaces NICE interventional procedure guidance 116.

This guidance has been incorporated into the NICE pathway on colorectal cancer, along with other related guidance and products.

We have produced a <u>summary of this guidance for patients and carers</u>. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes since publication

5 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

38) 日本腹膜播種学校-1

従来、腹膜偽粘液腫は臨床的にindolentな経過をたどるため、症状を緩和する手術が漫然とおこなわれてきた。このような緩和的手術では患者は長期間にわたり何回もの手術を受けるためQOLは不良で、体内から癌が消えることはない。そのため腫瘍による臓器圧迫によるイレウス・瘻孔形成による感染や出血などにより長期入院の末死亡する例が多くみられた。そこで我々は1992年から腹膜偽粘液腫にたいし、本邦で初めて腹膜切除+術中温熱化学療法を臨床に導入した。この治療法は非常に高度な手術技術と術後管理が必要なばかりでなく、幅広い腫瘍学・栄養学・抗がん剤・解剖・生理学的・緩和医療や消化器手術以外の泌尿器科的・婦人科的知識を必要とするため包括的治療(Comprehensive treatment)と呼ばれている。

過去20数年間の多数例の包括的治療後の長期予後解析から、腹膜偽粘液腫に対する腹膜切除+術中温熱化学療法はこの疾患の予後を改善させるきわめて有効な方法であることが判明した。

そこで、この方法を日本で広く広めるため、2016年から日本腹膜播種治療学校を開設することになった。

日本腹膜播種治療トレーニング プログラム

Japanese School of Peritoneal Surface Oncology And Japanese Peritoneal Surface Oncology Training Program A Joint Venture of Peritoneal Surface Oncology Group International European Peritoneal Surface Oncology Training Program Web Site:

ESPSO:http://www.essoweb.org/eursso/education/ool-of-peritoneal-surface-oncology-espso/8-education/244-european-school-of-peritoneal-surface-oncology-training-programme.html

PSOGI: http://www.psogi2016.com/index.php?id=17

日的

腹膜播種に関する基礎的・臨床的知識の習得、エビデンスに基づいた腹膜播種の包括的治療の習得

Peritoneal Surface Oncologyとは

腹膜播種の発生機構を分子生物学的あるいは病理学的に研究するとともに、その診断方法や治療法を開発する分野である。 対象疾患

腹膜播種を有する疾患と,播種はないが細胞診陽性例

胃癌・大腸癌・虫垂癌・卵巣癌・腹膜偽粘液腫・子宮癌・膵癌・胆管癌・胆嚢癌・肝臓癌からの腹膜播種・原発性腹膜癌・腹膜中皮腫・のう 胞性中皮腫・顆粒細胞腫・肉腫などを対象とする。

Peritoneal Surface Oncology Group International (PSOGI)とEuropean Society of Surgical Oncology (ESSO)が後援する European School of Peritoneal Surface Oncology (ESPSO)が2013年に設立された。JSPSOはPSOGOとESPSOの支部として2016年9月1日に開校する。

近年、腹膜播種にたいし腹膜播種をすべて切除する外科手術と周術期腹腔内化学療法を組み合わせた包括的治療が開発された。従来は不治の病と考えられてきた腹膜播種が、この包括的治療により目を見張るばかりの治療成績の改善が得られるようになった。この包括的治療を安全にかつ高い治癒率をめざして行なうためには、外科腫瘍学・解剖学・生理学・病理学・化学療法・外科手術手技(外科・婦人科・泌尿器科領域)・術後管理における豊富な知識と経験が必要である。しかしながら、従来から行なわれてきた外科トレーンニングのみでこの治療を行なうと患者にかかるリスクが高いと考えられている。

そこで、この包括的治療を初心者が修得できるようにするために2016年9月1日からJSPSOが開校する。その後援を行なうPSOGIは腹膜播種の治療で世界を牽引するグループであり、腹膜播種の国際規約分類・データ解析・新しい治療法の開発を行なってきた。また、1998年から2年おきに国際学会を開催し、包括的治療の普及に貢献してきた。

JSPSOの機構と指導医

JSPSOの代表は米村豊(Mail: y.yonemura@coda.ocn.ne.jp)である。

委員会とそのメンバー

研修内容の作成・指導医の選択・認定・その他をおこなう。メンバーはPSOGIの幹事と日本の委員数名である。

片山寛次、石橋治昭、水本明良、左古昌蔵、藤村隆、鍛利幸、遠藤良夫、村田聡 (日本)、

Paul H Sugarbaker (USA), Emel Canbay (Turkey), Brendan Moran (UK), Marcello Deraco (Italy), Santiago Moreno-Gonzalez (Spain),, Haile Mahtem (Sweden), Pompiliu Piso (Germany), David L Morris (Australia), Frans A.N. Zoetmulder (the Netherland), Oliver Glehen (France), Beate Rau (Germany), Françoir Gilly (France), Yan Li (China), Dominique Elias (France), David Bartlett (USA), Vic Verwaal (Denmark), Kurt van del Speeten (Belgium), Mao-Chi Shier (Taiwan)

JSPSOは研修希望者にたいし腹膜播種に関する基礎的・臨床的トレーニングを行なう。終了後は研修者には卒業修了書が与えられる。研修者はカンファレンスに参加し、患者のプレゼンテーションをおこない、手術適応・治療法の選択などを学ぶ。また、多数の治療経験のあるhigh volume centerで腹膜切除と温熱化学療法に参加し、術後管理も習得する。

習得する内容

術前審査腹腔鏡と腹膜播種係数の診断・腹腔鏡下温熱化学療法の方法。

術前化学療法特に術前・腹腔内・全身化学療法・腹腔ポート挿入法・副作用対策

手術適応 除外症例

腹膜切除の手順・腹腔内洗浄療法

術中温熱化学療法の方法と副作用対策

術後早期腹腔内化学療法

切除標本の切り出し方法。病理診断と疾患別の免疫パネル。腹膜播種特異遺伝子

術後管理の方法

術後化学療法とフォローアップ法

統計処理の方法

学会発表・論文作成・プロトコール作成と倫理委員会への提出

などを研修する。

研修者の経験年数や技量にもよるが、60~130例以上の手術に参加する必要がある。

2年に一回開催されている国際学会Peritoneal Surface Oncology Group Internationalか、年1回行なわれる日本ハイパーサーミア学会の温勢

38) 日本腹膜播種学校-2

療法トレーニングコースに参加する。

また、学会発表や審査が行なわれる英文論文を投稿する。この論文が卒業論文となる。

また、PSOGIの幹事の海外の施設での短期研修も行なうことができる。。

研修資格

日本の医師免許を有し、腹膜播種の治療に興味がある医師。卒後初期研修を終了した医師。外科医・産婦人科医・麻酔医・画像診断医など。

外国人医師であっても研修病院が厚生省からの研修許可病院であれば研修可能である。

研修期間

6ヶ月-3年間。研修者の希望と立場により変更可能(週2日なども可能)。

研修方法

経験豊富な指導医が直接指導に当たる。指導内容は術前診断・患者選択と手術適応・周術期化学療法・術後管理・術後フォローアップ・病理診断・学会発表・論文の作成などである。指導医は研修者が完全に上記のことが終了するまで責任を持って指導に当たる。

福井大学医学部附属病院がん診療推進センター

岸和田徳洲会病院・腹膜播種センター

草津総合病院・腹膜播種センター

滋賀医科大学・腫瘍センター

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