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Title Autologous breast reconstruction methods as alternatives to breast implants

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Aim

The HAS performed this assessment at the request of the Ministry of Health, which wishes to expand the reimbursable care provision available to women for breast reconstruction (BR) in a cancer context, against a backdrop of a reduction in breast implant (BI) reconstruction provision in France following the development of cases of Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) and the market withdrawal of macro-textured and polyurethane-coated implants.

The assessment focused on, firstly, the efficacy and safety, as well as the practice requirements, of seven strictly autologous BR methods not yet reimbursed in France (with free flaps located in the thigh [two], buttock [three], abdomen [one] and with a pedicled thoracodorsal flap), and, secondly, specific aspects of three methods that are already reimbursed (autologous fat grafting: oncological safety associated with performance on the contralateral breast (for symmetry) and anaesthetic safety associated with performance of serial fat grafting; latissimus dorsi flap reconstruction: distinction to be made between the various methods; breast-sharing technique: residual indications in 2019).

Conclusions and results

Analysis of the literature demonstrated that the original studies are predominantly retrospective, non-comparative, single-centre studies on small, relatively heterogeneous populations and/or describing the early results of a surgical team. These are therefore studies with a high risk of bias and a low level of evidence. Meta-analyses were only found for autologous fat grafting.

The working group provided its argued expert opinion relating to the different components of the assessment in view of French practices.

As regards the various flap methods, on the basis of these data (literature and expert opinions) it is concluded that:

1) The following autologous flap methods are surgical methods that may be proposed:

- the free abdominal-based superficial inferior epigastric artery (SIEA) flap, indicated only if preoperative imaging data reveal superficial inferior epigastric vessels of superior quality to the deep inferior epigastric vessels;
- anterolateral thigh free flaps using a transverse musculocutaneous gracilis (TMG) flap or a profunda artery perforator (PAP) fasciocutaneous flap, suggested as a priority to women (generally relatively young and slim) for immediate reconstruction, including bilateral reconstruction, following a prophylactic mastectomy;
- the pedicled thoracodorsal artery perforator (TDAP) fasciocutaneous flap, without a breast implant, totally sparing the latissimus dorsi (LD) muscle, obtained by a fine and expert dissection;
- minimally invasive pedicled autologous musculocutaneous LD flaps (ALD), in particular the MSLD (muscle-sparing) flap that very largely spares the LD muscle.

2) A differentiation needs to be made in the care provision between reconstruction using an pedicled autologous LD musculocutaneous flap without a breast implant and the same procedure but with an implant.

3) The breast-sharing method should no longer be included in the methods to be offered to women wishing breast reconstruction.

4) Free gluteal flap methods (including SGAP, IGAP and FCI) should not be added to the methods to be proposed.

5) Autologous fat grafting (lipofilling) may be used for a contralateral symmetry procedure following cancer-related reconstructive or oncoplastic breast surgery in the following conditions:

- patient wishing this injection in the contralateral breast to perfect her BR;
- proposition that may not be made by the surgeon alone but requiring the favourable opinion of another physician, primarily the patient's oncologist;
- existence of a normal complete preoperative assessment including mammography and ultrasound exams, as well as MRI (particularly after lumpectomy), performed in the past three months;
- absence of genetic, family or personal predisposition to breast cancer;
- optimal cancer treatment with respect to the recommended protocols;
- patient informed about the potential residual cancer risk, which cannot currently be estimated in the absence of data.

Autologous fat grafting, widely used in BR, either in addition to any other reconstruction method or exclusively, should meet the following conditions:

- sessions at minimum intervals of 2 to 3 months;
- total number of sessions depending on the surgical context, and not exceeding six sessions, including as an exclusive BR method on irradiated skin;
- continuation of lipofilling should be discussed each time with the patient.

The optimal conditions for the performance of autologous methods, partially defined in the literature, based mainly on analysis of reimbursement databases and expert opinions, consist of:

1) As concerns free flap methods:

- double surgical team to operate simultaneously on both surgical sites; each trained and experienced in this type of surgery and including at least one surgeon and a surgical assistant, with one of the surgeons qualified in microsurgery and supported by a scrub nurse (trained operating theatre nurse);
- need for more surgical personnel in the event of bilateral BR (three to four surgeons), with longer occupation of the operating theatre (at least 8 hours);
- need to have access to magnifying glasses and a surgical microscope and, if possible, equipment for assessment of flap perfusion (use of indocyanine green); preoperatively, depending on the location of the flap to be harvested, need for imaging assessment to visualise anatomical vascularisation;
- need for close postoperative monitoring by nursing staff every hour for the first 24 hours, in a high-dependency (HDU) or (in delayed breast reconstruction only) in the postoperative recovery room for 6 hours with an automated system (sensors or ultrasound) then in a ward room with continuation of this system and monitoring by nursing staff every 2 hours;
- hospital organisation enabling emergency access to the operating theatre for further surgery, in particular decided upon in view of the signs detected by the monitoring described above;
- mean hospitalisation duration of 5 to 7 days, and up to 10 days for bilateral BR.

2) As concerns thoracodorsal pedicle-based flap reconstructions:

- mean hospitalisation duration of 3 to 4 days for minimally invasive methods, and for non-minimally invasive LD methods if pre-anaesthesia analgesic management using a nerve block has been administered (and 6 days otherwise), with discharge possible for home hospitalisation or home nursing care;
- for the TDAP method, during the longer muscle-sparing dissection step, need for magnifying glasses and a scrub nurse.

3) In the current context encouraging immediate reconstructions, including prophylactic mastectomy situations, it is preferable to differentiate these from delayed reconstructions in order to take into account the multiplicity of oncological and reconstructive procedures performed during the same operating time.

Recommendations

This assessment makes it possible to recommend the registration for reimbursement of the following autologous breast reconstruction methods: SIEA, TMG, PAP, TDAP and minimally-invasive ALD (MSDL), to define their practice requirements and to improve the safety of autologous fat grafting, in order to expand the reimbursable care provision available to women, and to monitor the evolution of practices in France.

In addition, it is recommended that the choice between the different breast reconstruction methods be based on a shared decision-making process between the healthcare professionals and the patient. This decision must be based on clear and truthful information of the patient concerning all available techniques, at the same time explaining the specific characteristics in view of her own personal condition (morphotype, oncological and medical criteria, age, etc.). Information documents for women will be produced for this purpose.

Method :

This work followed a standard assessment method based on:

- critical analysis of data from the literature identified after a systematic literature search and selected on the basis of explicit criteria;
- the supported position of a multidisciplinary working group composed of experts, healthcare professionals involved in BR (plastic surgeon, gynaecological surgeon and/or oncologist, anaesthetist, operating theatre nurse, oncogenetics specialist, from private and public sectors) and patients;
- analysis of activity and reimbursement databases to determine hospitalisation durations for breast reconstruction.

Then, during a draft report review phase, the HAS collected:

- comments from the French National Cancer Institute (INCa);
- the viewpoints of French national councils for healthcare professionals (CNP) and the learned societies concerned, consulted as stakeholders, regarding the clarity, readability and consistency of the report.

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