

Surgical Outcomes and Practice

Caution is required in interpreting the information as:

- 1) Mr. Ian Paterson carried out a procedure that was unrecognised and unapproved and there is therefore no other information to draw upon.
- 2) Mr. Paterson's record keeping was not clear, making analysis difficult.
- 3) Treatment of patients were adapted on a case by case basis because of the type of surgery Mr. Paterson carried out, as other clinicians attempted to compensate for poor surgery.
- 4) There are major differences in the characteristics of patients and their tumours – this as well as the type of surgery has an impact on outcomes.
- 5) Many patients have had their surgery in the relative recent past and therefore long term information is not available.
- 6) Many patients have had further treatment.

Summary:

- Over 1000 NHS patients are believed to have been treated with a mastectomy by Mr. Ian Paterson between 1994 and 2011.
- Mr. Paterson carried out an unrecognised and unapproved procedure that has been described by some as a 'cleavage sparing mastectomy' (CSM) without their consent.
- The most comprehensive information is available on patients who have had single primary invasive breast cancer. The West Midlands Cancer Intelligence Unit has undertaken an analysis of this group (237 patients with CSM; 768 patients in total). The figures below outline the findings:
 - The data suggests that overall mortality in the CSM group (9.3%) is similar to the group who had a mastectomy (8.6%).
 - The data from the West Midlands Cancer Intelligence Unit shows that this unapproved procedure puts patients at risk in the long term.
 - The data suggests that Mr. Paterson performed the unapproved procedure on patients who tended to have a good chance of recovery (good prognosis).
 - The analysis suggests that in patients who underwent the unapproved procedure (CSM) there is an increased risk of the cancer returning to the same site (local recurrence) in the long term, requiring further treatment.
 - The West Midlands Cancer Intelligence Unit highlights that further investigation is required in the cases of patients where it cannot be determined if they had a CSM or not, and for patients with multiple primary breast cancers.
 - Patients will continue to be monitored and reviewed on an individual basis and follow up will be for a far longer period than is traditional - at least 15 years based on present information.

Heart of England NHS Foundation Trust has been using the information made available through the recall process to establish the best advice for patients regarding ongoing monitoring and treatment.

The Trust has carried out:

- 1) A **review** of all NHS patients believed to have had a mastectomy under the care of Mr. Paterson – **1071**.
- 2) A **recall** of the above patients who were still alive and willing to have a physical clinical review – **642 patients** of whom **553** attended the recall clinics.
- 3) A detailed **analysis** of the information, in collaboration with the West Midlands Cancer Intelligence Unit, of those patients on whom the mastectomy was performed on the **primary breast cancer** – **895 patients**.

In these 895 patients:

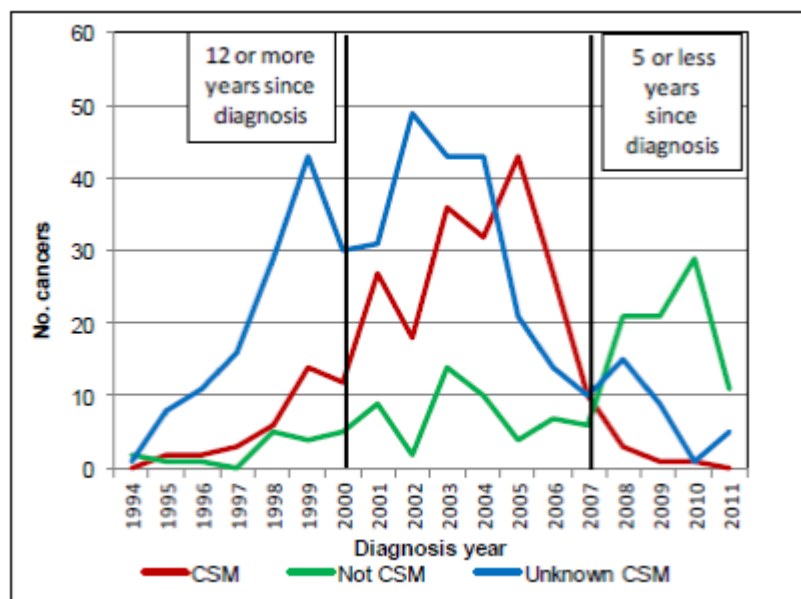
86 patients had multiple primary breast cancers

8 male patients

801 individuals had single breast cancers:

- 33 patients had non-invasive cancers
- 768 patients had single invasive cancers

By analysing those patients with single invasive cancers (the largest group of patients) we have established an apparent pattern for the operations that Mr. Paterson carried out over the years of his practice and this is shown below:



Variation in CSM status by year of diagnosis

What other information therefore do we know at this stage?

Clinical experts have been involved in a process during which they have reviewed patients, their notes, treatment and results of tissue samples and investigations. The team has been able to draw the clearest picture of the potential impact in those women with a single primary invasive breast cancer (768 patients).

In this group:

152 patients could be confidently described as having had a mastectomy.

In 237 women, the clinical team felt confident that excessive breast tissue remained after the operation – this suboptimal mastectomy has been described by some as a “cleavage sparing mastectomy” (CSM).

In 379 patients, it was not possible to determine the precise nature of the operation.

Local breast cancer recurrence rates (including local lymph nodes)

At 5 years:

- In individuals who have had a CSM, local recurrence rates were 4.6%
- In individuals in whom the type of surgery was unclear, local recurrence rates were 3.4%
- In individuals who have had a mastectomy, local recurrence rates were 2.0%

At 12 years:

At the time the information was analysed only a small proportion of individuals had been followed up for 12 years.

- In individuals who have had a CSM, recurrence rates were 11.4%
- In individuals in whom the type of surgery was unclear, local recurrence rates were 4.2%
- In individuals who have had a mastectomy, local recurrence rates were 2.0%

Secondary Cancer away from the breast (Distant Metastases)

At 5 years:

- In individuals who have had a CSM, distant recurrence rates were 4.2%
- In individuals in whom the type of surgery was unclear, distant recurrence rates were 7.9 %
- In individuals who have had a mastectomy, distant recurrence rates were 2.6%

At 12 years:

At the time the information was analysed only a small proportion of individuals had been followed up for 12 years.

- In individuals who have had a CSM, distant recurrence rates were 5.9%
- In individuals in whom the type of surgery was unclear, distant recurrence rates were 13.2%. This was felt to be consistent with the poorer prognosis of the cancers in this group, so caution should be taking in drawing definitive conclusions.
- In individuals who have had a mastectomy, distant recurrence rates were 3.3%