

## VIEWPOINT

## What should be the management policy for asymptomatic inguinal hernias?

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### Abstract

Elective surgical repair was the general policy for the treatment of asymptomatic and minimally symptomatic inguinal hernias, based on reducing the risks of possible future bowel obstruction or visceral strangulation. Two randomized controlled trials in 2006 suggested that an alternative policy of “watchful waiting” was safe and appropriate. As a result, some health authorities in the UK withdrew funding for elective surgical repair for asymptomatic hernias in 2010. The long-term follow-up results of these two trials, however, showed high rates of surgery in the watchful waiting arms due to the development of symptoms. Two recent studies have called the watchful waiting policy into question on the basis of cost-effectiveness, quality of life and mortality data.

The current article shows the results of an Official Information Act request of the New Zealand Ministry of Health and the 20 District Health Boards on their current policies for the management of such hernias. The results show a range of policies, with two District Health Boards employing watchful waiting, seven with policies or health pathways that can restrict or deny access to treatment, and all District Health Boards required to comply with Ministry of Health performance indicators. It is concluded that, at least with some District Health Boards, patients with asymptomatic and minimally symptomatic inguinal hernias are given a lower priority for surgical treatment than they might merit on clinical grounds. Further research is needed to formulate appropriate policy for the management of this common disorder, and should perhaps be extended to cover other similarly common conditions.

### Background

Until about 8 years ago it was generally believed by surgeons and the wider medical community in countries with Western-style healthcare systems that early Elective Surgical Repair (ESR) was indicated for inguinal hernias. The reasons were to reduce the associated pain for symptomatic hernias and the risks of the acute complications of bowel obstruction and visceral strangulation for all such hernias. These complications have high associated morbidity and mortality rates, even for asymptomatic and minimally symptomatic inguinal hernias.<sup>1</sup> These two groups are practically inseparable in routine clinical management. The general belief, however, was not based on a sound knowledge of the natural history of Asymptomatic and Minimally Symptomatic Inguinal Hernias (A&MSIH) or on cost, risk and benefit analyses of management options.

In 2006, two prospective Randomised Controlled Trials (RCTs) were published, which challenged this belief. One was from the USA the other was from the UK.<sup>2,3</sup> They compared ESR with no surgery but a regular surveillance programme called Watchful Waiting (WW). They showed that, after follow-up periods of 2 to 4.5 years and 1 year respectively, the incidences of acute complications requiring emergency surgery were small, and concluded that WW is an acceptable option for men with A&MSIH. Furthermore, a cost-effectiveness analysis was also performed on the USA RCT participants at 2 years of follow-up.<sup>4</sup> This concluded that WW is a cost-effective treatment for men with A&MSIH.

Around the same time, support for the WW policy came from another quarter. The replacement of sutured hernia repair techniques with the use of tension-free prosthetic meshes had already been shown to have produced a substantial reduction in hernia recurrence rates after both elective and acute surgery.<sup>5,6</sup>

Following this important advance, attention shifted onto the issue of chronic postoperative pain after inguinal hernia surgery, which was shown to correlate with types of hernia repair materials, and with operative and patient-related factors.<sup>7</sup> The claimed high incidence of such chronic pain added support for the WW policy for patients presenting with A&MSIH.

The results of the USA and UK RCTs, and concerns about chronic postoperative pain, led the European Hernia Society to publish guidelines recommending WW as the first-line management for A&MSIH in men.<sup>8</sup> They did not, however, describe how this policy might be effectively implemented.

These developments were seized-on by some health administrators in the UK and elsewhere, who were aware that:

- (i) Inguinal hernias are very common;
- (ii) Up to one-third are asymptomatic or minimally symptomatic;
- (iii) Elective inguinal hernia repair is the most frequent operation performed by general surgeons; and,
- (iv) The need for such surgery will probably increase with future population aging.<sup>9,10</sup> They therefore sought ways to reduce spending on this costly part of the health budget by having WW (as opposed to ESR) accepted as the policy for the management of A&MSIH. In 2010 this policy change was implemented by the clinical commissioners of the UK National Health Service, who withdrew funding for ESR for such hernias.<sup>11</sup>

The new WW policy for the management of A&MSIH was also supported by an extensive literature review in 2011, which concluded that it is safe for fit men under 50 years of age, with signs for more than 3 months. This review also concluded that the WW policy is cost-effective but found no difference in chronic pain and quality of life measures between WW and ESR.<sup>12</sup>

The long-term follow-up results of the UK RCT were published in 2011; those of the USA RCT in 2013. The UK RCT reported on participants followed-up for a median of 7.5 years and found an estimated crossover rate of 72% from the WW arm to the ESR arm, mostly due to pain. The authors concluded that most patients with painless inguinal hernias develop symptoms over time, and therefore recommended ESR for medically fit patients with A&MSIH.<sup>13</sup>

After an additional 7 years of follow-up, WW randomised participants in the USA RCT had a high estimated rate of proceeding to ESR, 68%, mostly related to pain. Participants over 65 years had a higher rate again, 79%, compared to 62% for younger participants. There was also the need for a small number of emergency operations in the WW group but no associated mortality. The authors concluded that men who present with an inguinal hernia, even when minimally symptomatic, should be counselled that although WW is a reasonable and safe policy, symptoms are likely to progress and an operation will be needed eventually.<sup>14</sup>

Two recent studies have raised concerns about the WW policy. In 2013, a Swedish prospective study was published of participants having open inguinal hernia repair surgery showing that, at 12 months follow-up, 77.2% had less groin pain and 5.4% had increased groin pain. Overall, however, symptoms and quality of life measures improved in the majority of participants, and treatment was cost-effective regardless of pre-operative symptom severity. The authors criticised the USA and UK RCTs on the grounds that in the former trial only 10% of screened men were entered into the ESR arm, and that the latter trial only included men over 55 years of age.<sup>15</sup>

This year a retrospective study from the Birmingham and Solihull primary care trust in the UK was published, which defined some unintended consequences of the WW policy. It compared the outcomes for patients having inguinal hernia repair surgery during the 16-month period immediately

before a WW policy was introduced, with those having such surgery during the 16-month period immediately afterwards. The WW policy was associated with a higher incidence of adverse clinical outcomes after its implementation: overall adverse events 18.5% compared to 4.7%, emergency surgical repairs 5.5% compared to 3.6%, and higher mortality 5.4% compared to 0.1%.

Whilst conceding some weaknesses in their study design, and that their data did not establish a causal link between the WW policy and the adverse outcomes, the authors concluded that the policy may be putting patients at risk and might increase overall costs. They also criticised the USA and UK RCTs on the basis that the regular specialist surgical follow-up of participants in the WW arms, and high crossover rates to the ESR arms in both studies, indicated that they may not reflect 'real world' practice.<sup>11</sup>

From these recent developments it appears that we have nearly come full circle. Certainly we know more about the natural history of A&MSIH than we did before. The evidence base for the WW policy is in doubt, however, and might become more so, as future advances in laparoscopic and open surgical techniques, and new repair materials are increasingly employed.<sup>16</sup> Further research is clearly needed now to verify the results of the most recent studies and to formulate appropriate policy for the surgical management of A&MSIH.

## New Zealand management policies

What are the implications for the management of A&MSIH in New Zealand? To investigate this issue the Chief Executive Officers of the Ministry of Health and the 20 District Health Boards (DHBs) were sent an Official Information Act request on 25 July 2014 asking the question: “..... *whether the [Ministry of Health or DHB] has a policy for the management of asymptomatic inguinal hernias? If so, what is it, who was involved in developing it, and on what evidence was it based?*”

**Table 1. Responses from health authorities to Official Information Act requests on their policies for management of asymptomatic inguinal hernias (2014)\***

Health authority (response dates)	Management policy for asymptomatic inguinal hernias	Those involved in policy development	Evidence base for policy
Ministry of Health (1 Aug)	No policy.	NIP	NIP
Auckland DHB (5 Aug)	No policy. Symptomatic and asymptomatic hernias seen and surgery offered if medically appropriate.	NIP	NIP
Bay of Plenty DHB (19 Aug)	From referral letters surgeons assign a clinical priority for an assessment. Not all asymptomatic hernia may have the same priority. This priority is matched to “financially sustainable threshold” criteria to be seen.	NIP	NIP
Canterbury & West Coast DHBs (20 Aug)	CDHB Health Pathways March 2014: “Christchurch Hospital does not usually take referrals for hernias unless they are large and significantly symptomatic e.g., persistently painful or causing difficulty with micturition”.	Health Pathways Document Owner: General Surgery Team	NIP
Capital & Coast DHB (27 Aug)	Patients referred are assessed against clinical assessment criteria. Where they do not reach threshold as with majority of asymptomatic hernias they are referred back to GP. GPs advised that should condition deteriorate or they have concerns, to re-refer back.	NIP	NIP
Counties Manukau (25 Aug)	All inguinal hernia referrals, including asymptomatic, seen. Treatment offered according to individual patient clinical criteria, risks and potential benefits.	Discussion with Clinical Head of General Surgery	NIP
Hawke’s Bay DHB (31 Jul)	No Policy.	NIP	NIP
Lakes DHB (12 Aug)	No policy.	NIP	NIP

MidCentral DHB (31 Aug)	Asymptomatic referrals which do not meet prioritisation score are referred back to GPs for re-referral if they become symptomatic.	NIP	NIP
Nelson & Marlborough DHB (15 Aug)	Adult Health Pathways: “these guidelines are clear that asymptomatic inguinal hernias do not require treatment and are declined unless other individual significant issues are related to this.”	Health Pathways Document Owner: General Surgery Team	NIP
Northland DHB (20 Aug)	Symptomatic referrals accepted but watchful waiting for A&MSIH.	NIP	NIP
South Canterbury DHB (25 Aug)	Aoraki Health Pathways for Adults, July 2012: “Hernias are low priority and may not be seen unless they are large and significantly symptomatic.”	Based on CDHB Pathways and reviewed by local surgeons to meet local requirements.	Ref <sup>20</sup> cited.
Southern DHB (18 Aug)	No policy. Each case is assessed by a clinician and along with CPAC the treatment plan is made.	NIP	NIP
Tairāwhiti DHB (19 Aug)	No policy. All hernia referrals seen whether symptomatic or asymptomatic. Surgery is offered to those that are medically appropriate.	NIP	NIP
Taranaki DHB (8 Aug)	No policy	NIP	NIP
Waikato DHB (4 Aug)	No policy. All referrals prioritised by clinicians. Surgery not offered for most asymptomatic inguinal hernias but referred back to GPs for re-referral if condition deteriorates.	NIP	NIP
Wairarapa & Hutt Valley DHBs (19 Aug)	No policy for either DHB. But Health Pathways for Hutt Valley DHB say “Publicly funded treatment is not currently offered for patients with: <ul style="list-style-type: none"> <li>▪ symptomatic inguinal or umbilical hernias</li> <li>▪ asymptomatic hernias”.</li> </ul>	NIP	NIP
Waitemata DHB (7 Aug)	No policy	NIP	NIP
Whanganui DHB (1 Aug)	Since 2008 a “watch and wait” approach.	“ .. in line with the policy developed by Waikato Hospital.”	Refs <sup>2,3 &amp; 4</sup> cited.

**Legend:** \*PDF copies of responses available from the author on request. NIP - No Information Provided. CPAC – Clinical Priority Assessment Criteria. CDHB – Canterbury District Health Board.

Table 1 shows a surprising range of management policies. At one end of the range there was access to assessment and possible surgery for patients with A&MSIH who were deemed medically appropriate, through an apparently middle ground of WW, to refusal to see and assess patients for treatment at the other end. What is not clear from these data, however, is whether what was claimed to be WW, included initial specialist assessment and regular appropriate clinical reviews thereafter or was, in practice, no different from refusal to see and treat.

Table 1 also points to some inconsistencies. For example, Wairarapa & Hutt Valley DHBs reported no policy but the latter had a version of Health Pathways, which made clear to general practitioners (GPs) that referrals for A&MSIH were not accepted. Hawke’s Bay DHB also reported no specific policy in their Surgical Referral Acceptance Guidelines and categorised “most abdominal hernias” as “Routine”, resulting in referral for ongoing assessment and management back to the patient’s GP. These data, however, do not show how many other DHBs had similar referral pathway constrictions and obstructions, and how much DHB policies differed from day-to-day practices. It is also noteworthy that Whanganui DHB’s “wait and watch” approach was said to be in line with Waikato Hospital policy, when the latter DHB claimed to have no policy.

## Conclusions

It is easy to understand how this confused picture has arisen. DHBs find themselves in an invidious position in a perfidious environment. They are forced by central government to make short-term strategic decisions to reduce elective healthcare for non-life-threatening disorders to keep within budget whilst, at the same time, appearing publicly to still provide universal access healthcare. Until recently this was achieved by prioritisation through CPAC and financial thresholds.<sup>17</sup> To this was added the National Waiting Times standards, as currently embodied in the Elective Services Performance Indicators, to which all DHBs must adhere.<sup>18</sup> Recently Health Pathways have started appearing. These are supposedly helpful and educational. A real motivation, however, is to work hidden from public gaze “..... to alter the trajectory of demand”.<sup>19</sup> The WW policy, by legitimising delay in treatment, fits well into this environment.

It is consoling to learn that we have not generally followed some UK authorities in accepting the WW policy for the management of patients with A&SMIH. Those of our DHBs who have embraced the policy, either overtly or covertly, should be aware that it is seriously in doubt. The story of the changing fortunes of the WW policy should teach us all the lesson that sudden policy changes in the management of common disorders should only be made on the basis of broad research findings, not on short-term outcome data. Also, all policies should be regularly reviewed in the light of new research findings.

Inevitably there will be speculation on whether there are similarly wide inter-DHB ranges of policies for the management of other common surgical disorders such as symptomatic cholecystolithiasis and haemorrhoids. If so, they might cause wide disparities in levels of access to treatment and clinical outcomes. Further research is needed to address these speculations.

## Summary

Although only two DHBs indicated that they have adopted the WW policy, seven have declared policies or health pathways that can seriously restrict or deny access to effective surgical treatment, and all DHBs must comply with performance indicators laid down by the Ministry of Health. It is therefore likely that, at least in some DHBs, patients with A&MSIH are ascribed a lower priority, and are less likely to receive surgical treatment, than they might well deserve.

**Competing interests:** None.

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