



What a mesh! An Australian experience using national female continence surgery trends over 20 years

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Abstract

Purpose To review the evolution of female continence surgical practice in Australia over the last 20 years and observe whether vaginal mesh controversies impacted these trends.

Materials and methods From January 2000 to December 2019, medicare benefit schedule codes for female continence procedures were identified and extracted for: mesh sling, fascial sling, bulking agent, female urethral prosthesis, colposuspension, and removal of sling. Population-adjusted incidences per 100,000 persons were calculated using publicly available demographic data. Three discrete phases were defined over the study time frame for analysis: 2000–2006; 2006–2017, and 2017–2019. Interrupted time-series analyses were conducted to assess for impact on incidence at 2006 and 2017.

Results There were 119,832 continence procedures performed in Australia from 2000 to 2019, with the mid-urethral sling (MUS) the most common (72%). The majority of mesh ($n = 63,668$, 73%) and fascial sling ($n = 1864$, 70%) procedures were in women aged < 65 years. Rates of mesh-related procedures steeply declined after 2017 (initial change: -21 cases per 100,000; subsequent rate change: -12 per 100,000, $p < 0.001$). Non-mesh related/bulking agents increased from $+0.34$ during 2006–2017 to $+2.1$ per 100,000 after 2017 ($p < 0.001$). No significant change in mesh extraction was observed over 2006–2017 ($+0.06$ per 100,000, $p = 0.192$). There was a significant increase in mesh extraction procedures after 2017 (0.83 per 100,000, $p < 0.001$).

Conclusion Worldwide, controversy surrounding vaginal mesh had a significant impact on Australian continence surgery trends. The most standout trends were observed after the 2017 Australian class-action lawsuit and Senate Inquiry.

Keywords Surgical mesh · Mid-urethral sling · Stress urinary incontinence · Trends

Introduction

The use of synthetic polypropylene mesh in surgery dates back to the 1950s and has been adapted worldwide since the late 1990s for treatment of stress urinary incontinence (SUI) as ‘mid-urethral slings’ (MUS) [1]. With the relatively short learning curve and high success, it is not surprising that by

2002, the MUS became the preferred and most common surgery indicated for female SUI [2].

In 2003, the Therapeutic Goods Administration (TGA), an Australian regulatory authority for therapeutic goods including medical devices, approved the use of transvaginal mesh (TVM) for repair of pelvic organ prolapse (POP) [3]. TVM posed an exciting alternative to the traditional methods of using native tissue for POP repair, which had perceived higher surgical complexity, recurrence and failure rates. In 2011, concerns and controversy surrounding the safety and efficacy of the use of TVM for POP were raised [4]. A review by the United States of America’s (USA) food and drug administration (FDA) concluded that mesh repair for POP was not clinically superior to traditional native tissue repair and adverse events were ‘not rare’ [4, 5]. Lawsuits related to mesh complications accumulated in the USA [6], the FDA reclassified vaginal POP mesh as a class III (high risk) device, and in April 2019, all manufacturers

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were banned selling TVM products for POP [7]. In 2017, Australia saw the launch of two landmark events; a Senate Inquiry into safety of TVM (for both SUI and POP) in February and a class action lawsuit against manufacturer Johnson and Johnson in July [8, 9].

Unsurprisingly, uncertainty and anxiety exist for patients and referrers regarding TVM [10]. The MUS has fallen victim to this uncertainty, despite having a strong class I evidence base for its efficacy and safety and supportive position statements from the urological society of Australia and New Zealand (USANZ) and Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), among other international societies [11–13]. Despite the limitation in TVM for POP and single incision mini-sling for SUI, the MUS is still available for use.

The aim of this study was to review the evolution of female continence surgical practice following these landmark events by observing treatment trends over the last 20 years.

Methods

This was a retrospective population-based study utilising publicly available data from the services Australia medicare benefit schedule (MBS) and Australian bureau of statistics (ABS) databases. From January 2000 to December 2019, national data regarding the total number of female SUI procedures were extracted. Procedure numbers and MBS codes for the SUI procedures included: mesh sling (35,599), fascial sling (37,042), bulking agent (37,339), female urethral prosthesis (36,811), colposuspension (37,043 and 37,044), and removal of sling (37,340, 37,341, 35,581, 35,582, and 35,585). MBS definition of code 36,811 does not specify type of prosthesis and was included to capture data on possible urethral bulking agents not accounted for by individual codes. MBS codes only reliably record private practice procedures. Although the relative proportion of SUI procedures in private and public hospitals is not known, it is estimated that two-thirds of elective procedures are carried out in the private sector which allows for some approximation [14]. Data were stratified by year, age, and Australian state or territory. Included patients were female only, and were grouped into either < 65 or ≥ 65 years of age, to analyse the subgroup of elderly women [15]. Surgeries performed on patients aged < 35 years were minimal and excluded to capture relevant individuals who underwent procedures for SUI, where peak incidence is in older age groups.

Corresponding Australian demographic population data were obtained from ABS from 2000 to 2019, using estimated resident population from June 30th of the same year to relate to medicare data. All incidences were calculated as population-adjusted rates per 100,000 persons per year. The

incidence for women over the age of 35 years was standardised according to the corresponding state- and year-specific population obtained from ABS data. Standardised incidences were compared across procedures.

The time period analysed was chosen to be 2000–2019, spanning two decades. This captured the commencement of sling usage in 2000, and allowed for timepoints after the mesh class action lawsuit in 2017, to perform an interrupted time series analysis [8]. In addition, post-hoc analyses identified 2006 to be a peak of sling usage, and acted as an appropriate timepoint to distinguish between rising and stable usage. Therefore, three discrete phases could be characterised for analysis: uptake phase (2000–2006), where the procedure gained increasing awareness and popularity; stable phase (2006–2017), where the procedure was expected to be performed at a steady rate across years, and post-class action phase (2017–2019), after the initiation of the class action against mesh procedures.

Statistical analysis

Interrupted time-series analyses were conducted and assessed for impact on incidence at 2006 and 2017 for each procedure. Each phase was assessed for both change in level and change in trend. Level indicated the value of the series at the start of the segment (intercept), while trend indicated the rate of change of incidence (slope). A segmented ordinary least-squares regression model was used with Newey–West standard errors calculated to adjust for autocorrelation. Data analysis was performed using StataIC v.15.1 (College Station, TX), with the interrupted time-series analysis package from Linden et al. [16]. An alpha value of 0.05 was used to deem statistical significance in this study.

Results

From January 2000 to December 2019, there were 86,808 mesh sling procedures performed (Table 1). During this same period, there were 2664 fascial sling procedures, 9604 bulking agent procedures, 551 urethral prosthesis procedures, 20,205 colposuspension procedures, and 6531 removal of sling procedures. The majority of mesh sling ($n = 63,668$, 73%) and fascial sling ($n = 1864$, 70%) procedures were performed in women aged < 65 years, and this was consistent throughout all states and territories. Although bulking agent procedures were overall performed more in women ≥ 65 years, more were performed in younger women in South Australia (SA), Western Australia (WA), Tasmania (TAS), Australian Capital Territory (ACT), and Northern Territory (NT). Upon analysis by state or territory, the most mesh sling procedures were performed in New South Wales (NSW). Fascial slings were most performed in Victoria

Table 1 Numbers of continence-related procedures throughout Australia since 2000, by state or territory and age

Region	Procedure	Total <i>n</i>	Age	
			35–64 years	≥ 65 years
Australia	Mesh sling	86,808	63,668(73)	23,140(27)
	Fascial sling	2664	1864 (70)	800 (30)
	Bulking agent	9604	4465 (46)	5139 (54)
	Urethral prosthesis	551	292 (53)	259 (47)
	Colposuspension	20,205	16,026 (79)	4179 (21)
	Removal of sling	6531	4129 (63)	2402 (37)
New South Wales	Mesh sling	25,818	18,496 (72)	7322 (28)
	Fascial sling	572	365 (64)	207 (36)
	Bulking agent	2463	994 (40)	1469 (60)
	Urethral prosthesis	130	70 (54)	60 (46)
	Colposuspension	8622	6686 (78)	1936 (22)
	Removal of sling	1740	1007 (58)	733 (42)
Victoria	Mesh sling	19,233	13,666 (71)	5567 (29)
	Fascial sling	906	629 (69)	277 (31)
	Bulking agent	2617	1171 (45)	1446 (55)
	Urethral prosthesis	303	131 (43)	172 (57)
	Colposuspension	3056	2665 (87)	391 (13)
	Removal of sling	1225	749 (61)	476 (39)
Queensland	Mesh sling	20,816	15,140 (73)	5676 (27)
	Fascial sling	279	204 (73)	75 (27)
	Bulking agent	1442	719 (50)	723 (50)
	Urethral prosthesis	67	54 (81)	13 (19)
	Colposuspension	4850	3700 (76)	1150 (24)
	Removal of sling	1702	1103 (65)	599 (35)
South Australia	Mesh sling	7108	5345 (75)	1763 (25)
	Fascial sling	237	175 (74)	62 (26)
	Bulking agent	1719	886 (52)	833 (48)
	Urethral prosthesis	22	16 (73)	6 (27)
	Colposuspension	1560	1287 (83)	273 (18)
	Removal of sling	551	379 (69)	172 (31)
Western Australia	Mesh sling	10,243	8227 (80)	2016 (20)
	Fascial sling	173	139 (80)	34 (20)
	Bulking agent	993	500 (50)	493 (50)
	Urethral prosthesis	18	14 (78)	4 (22)
	Colposuspension	1627	1274 (78)	353 (22)
	Removal of sling	1058	714 (67)	344 (33)
Tasmania	Mesh sling	1994	1494 (75)	500 (25)
	Fascial sling	467	329 (70)	138 (30)
	Bulking agent	273	140 (51)	133 (49)
	Urethral prosthesis	4	2 (50)	2 (50)
	Colposuspension	237	188 (79)	49 (21)
	Removal of sling	190	130 (68)	60 (32)
Australian Capital Territory	Mesh sling	1183	931 (79)	252 (21)
	Fascial sling	16	11 (69)	5 (31)
	Bulking agent	88	46 (52)	42 (48)
	Urethral prosthesis	5	3 (60)	2 (40)
	Colposuspension	92	75 (82)	17 (18)
	Removal of sling	36	24 (67)	12 (33)

Table 1 (continued)

Region	Procedure	Total <i>n</i>	Age	
			35–64 years	≥ 65 years
Northern Territory	Mesh sling	413	369 (89)	44 (11)
	Fascial sling	14	12 (86)	2 (14)
	Bulking agent	9	9 (100)	0 (0)
	Urethral prosthesis	2	2 (100)	0 (0)
	Colposuspension	195	185 (59)	10 (5)
	Removal of sling	29	23 (79)	6 (21)

(VIC). Bulking agents were mostly performed in VIC. Removal of slings were mostly performed in NSW.

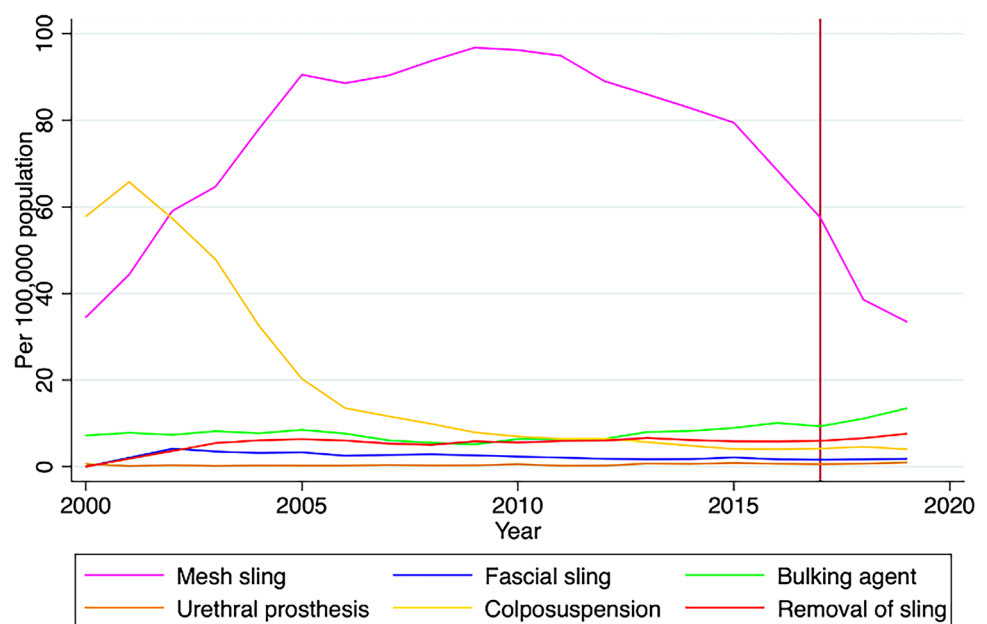
Across Australia, the rates of mesh sling procedures visually increased from 2000 to 2006, followed by a plateau, then a decline after 2017 (Fig. 1). Upon sub-stratifying data by state or territory, there was a visual decrease in rates of mesh sling procedures beyond 2017 across all states and territories (no statistical testing used; Supplementary Fig. 1). The observed increase in bulking agent use after 2017 was contributed by uptake in NSW, VIC, SA, and ACT (Supplementary Fig. 1).

Interrupted time-series analyses were performed across all included continence-related procedures from 2000 to 2019 (Supplementary Table 1). Upon analysis of mesh slings, there was an initial rate of 34.3 procedures per 100,000 persons, with an associated absolute increase of +11.0 procedures per 100,000 persons per year (95% CI 10.7–11.3, $p < 0.001$) during the uptake phase. During the stable phase, there was an observed decreasing trend

of -1.9 procedures per 100,000 persons per year (95% CI -3.6 – -0.2 , $p = 0.032$). In the post-class action phase, there was a significant immediate level change from the steady phase, of -21.4 procedures per 100,000 persons (95% CI -33.5 – -9.4 , $p = 0.06$), with a significant decreasing trend of -12.0 procedures per 100,000 persons (-14.45 – -9.60 , $p < 0.001$) (Fig. 2a). Upon analysis of bulking agent procedures from 2000 to 2019, there was an initial rate of 7.3 procedures per 100,000 persons, with an increase of +0.6 procedures per 100,000 persons per year (95% CI 0.0–1.1, $p = 0.048$) during the uptake phase. During the stable phase, there was a level change of -1.9 (95% CI -3.8 – 0.0 , $p = 0.050$), and a trend change of +0.43 (95% CI 0.0–0.7, $p = 0.043$). In the post-class action phase, there was a significant increasing trend of +2.07 procedures per 100,000 persons (1.9 to 2.3, $p < 0.001$) (Fig. 2b).

Interrupted time-series analyses of other procedures also demonstrated significant trend changes during the post-class action phase after 2017. The rate of fascial slings and

Fig. 1 Time series of continence procedures in Australia. The rates of continence-related procedures throughout Australia from 2000 to 2019 have been demonstrated, according to rate per 100,000 persons. Year 2017 has been indicated (vertical red line) to represent time of class action



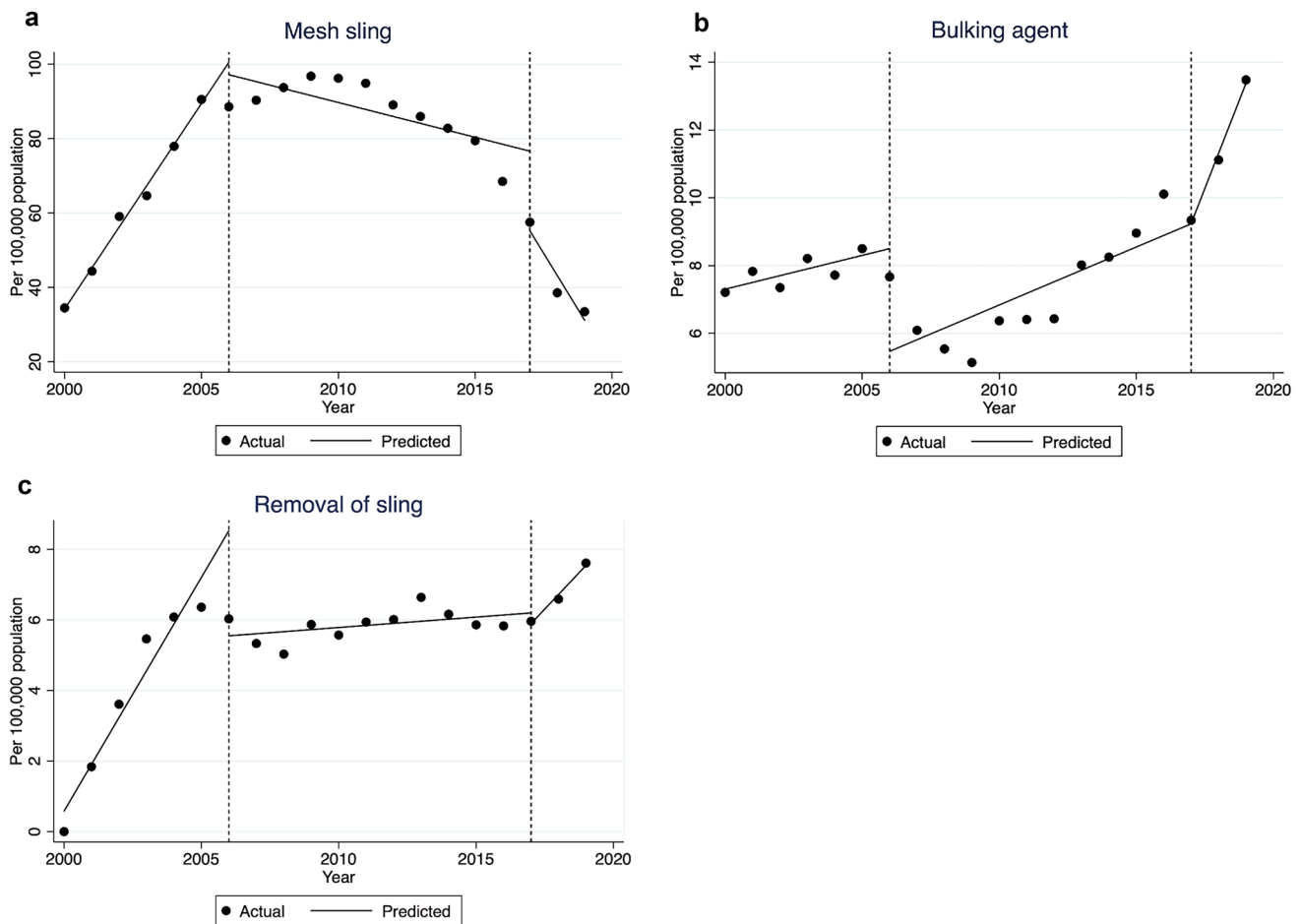


Fig. 2 Interrupted time-series analyses of mesh sling, bulking agent, and removal of sling procedures. Interrupted time-series analyses of mesh sling procedures (a), bulking agent (b), and removal of sling (c), performed throughout Australia from 2000 to 2019 have been demonstrated. Discrete phases have been marked by vertical dashed

lines, marking the uptake phase (2000–2006), stable phase (2000–2017), and post-class action phase (2017–2019). Ordinary least-squares regression models with Newey–West standard errors have been demonstrated for each phase

urethral prostheses significantly increased by 0.1 and 0.21 procedures per 100,000 persons per year. The removal of slings significantly increased by 0.83 per 100,000 persons per year (Fig. 2c).

Discussion

The surgical treatment of SUI in Australia has observed numerous changes in practice trends over the last 20 years. The three most marked changes were observed after 2017, including: a decrease in all mesh associated surgical treatment (MUS), an increase in non-mesh associated treatment and an increased number of mesh extractions. Importantly, this supports a possible association with the outcomes of two landmark Australian investigations related to the mesh controversy.

Overall, the results of this study demonstrated an upward trend in MUS of +11 per 100,000 women from 2000 to 2006, while there was a decline of –12 per 100,000 ($p < 0.001$) from 2017 onwards following landmark Australian events. The initial increase in MUS procedures is comparative to other studies in USA, Europe and Asia [17–19]. This international trend in uptake of MUS is likely attributed to the strong evidence base for effectiveness in treatment of SUI, with patient-reported subjective and objective cure of symptoms at 1 year up to 94% and 92%, respectively, in review by Ford et al. [20–22]. An additional factor favouring MUS may include the appeal and acceptability of a minor procedure with minimal recovery time required for patients.

Previous literature from the USA on trends in SUI related to the mesh controversy has captured a decline in rates of mesh-associated treatments following the initial FDA statement in 2011 [17]. Interestingly, this corresponds to an inflection point in this study, where mesh sling procedure

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numbers began to decline (Fig. 1). Although this would have been a contextually important analysis timepoint, we limited analysis to three phases to maximise datapoints per trendline and their respective confidence and significance. The steady decline of 1.9 cases per 100,000 from 2006 to 2017 observed in this study may relate to the development of these safety concerns. Zacche et al. similarly examined SUI procedure trends in United Kingdom (UK) from 2000 to 2017, where a 50% decrease in procedure rates was observed from 2008 to 2017 [23]. The impact of mesh media controversy towards surgical treatment trends is highlighted in 2013 study from Rice et al. which reported higher percentage of mesh complaints after 2011 FDA statement, with no difference in frequency of diagnosed mesh complications [24]. Similarly, Souders et al. studied an American complaints database from 2000 to 2014 and recorded the number of lawsuits almost triple from 2011 to 2013 [25].

The impact of USA position statements on public perception was evidenced in a study by Palmerola et al. observing trends in MUS, fascial slings and bulking agents from 2010 to 2017 [17]. They reported a decline in MUS procedures from 2011 to 2013 followed by an increase in uptake once again in 2014. This was found to coincide with American Urogynaecological Society (AUGS) and the Society of Urodynamics and Female Urology (SUFU) 2014 position statements; thus, these trends were attributed to the reassurance of the professional societies [17]. The decrease in mesh associated treatment of SUI observed in Australia after 2017 is likely associated to the population specific mesh controversy at the time, despite a consistent message on mesh safety from professional bodies [11].

Interestingly, there was an increase in all non-mesh associated treatment after 2017. The increase in bulking agent uptake observed in the results was similar to Zacche's findings; however, their results observed contrasting low and decreasing numbers of fascial sling procedures [23]. The observed increase in popularity of bulking agents in Australia may relate to RCT and meta-analysis studies comparing bulking agents with other procedures, observing similar patient satisfaction with bulking agents, but reduced cure rate compared with more invasive treatments [26, 27]. These studies suggest that bulking agents should not replace first-line traditional surgical treatment, but may have a role in certain patient groups including those not wishing to undergo invasive treatment, and robust long-term data are still not available.

There was a significant increase in number of mesh extraction procedures after 2017 ($p < 0.001$) which may be related to increased patient awareness following mesh controversy. This aligns with previous studies that have reported increase in revision or removal, including USA multi-centre study by Rac et al. which recorded a three-fold increase in mesh revision including removal from 2007 to 2013 [28].

The increase in mesh removal in Australia despite FDA statements suggesting the difficulty of mesh removal highlights the impact on quality of life that MUS complications may produce [4].

There are several limitations to the current data and analysis used. In Australia, MBS billings only reliably capture private-practice data, and thus, does not reflect public practice. They do not capture data on insurance, ethnicity, socioeconomic class or indication, and therefore, we cannot extract whether patients had surgery for primary SUI indication or prophylaxis with a concurrent procedure. Despite this, such data have been utilised in other domains to generate hypotheses and guide future studies [29, 30]. The utility of interrupted time-series analyses is limited by the lack of multivariable adjustment and restricted timepoints. In addition, data pertaining to functional outcomes, complications, cost, and associated morbidity were not available for further analysis. Nevertheless, this study presents novel findings in demonstrating updated trends beyond 2017 relating to the rates of continence-related procedures.

Conclusion

Worldwide controversy surrounding TVM had a significant impact on Australian practice trends for SUI procedures despite demonstrated safety of MUS. The commencement of the class-action lawsuit and Senate Inquiry into TVM for POP in 2017 had an important impact on SUI procedural trends. The medical community should endeavour to re-engage Australian women by continuing to provide evidence based care in discussion of MUS.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s00345-021-03691-9>.

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Author contributions AM: data collection and manuscript production, LQ: statistical analysis and manuscript production, GC: manuscript production and supervision, MP: manuscript revision and supervision, JB: manuscript production and supervision, EC: manuscript production and supervision, JG: manuscript production and supervision.

Data availability Accessed publicly available data from the Services Australia Medicare Benefit Schedule (MBS) and Australian Bureau of Statistics (ABS) databases.

Code availability StataIC v.15.1 (College Station, TX).

Declarations

Conflict of interest No conflicts of interest to declare.

Informed consent For this type of study, formal consent is not required as accessed publicly available data from the Services.

Australia Medicare Benefit Schedule (MBS) and Australian Bureau of Statistics (ABS) databases.

Research involving Human and Animals Participants This chapter does not contain any studies with human participants or animals performed by any of the authors.

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