Changing of the guard: Reducing infection when replacing neural pacemakers

Joshua Pepper MBBS[1], Lara Meliak MD[1], Harith Akram MBCHB[1], Jonathan Hyam DPhil[1,2], Catherine Milabo[1], Joseph Candelario BSc[1], Thomas Foltynie PhD[1], Patricia Limousin PhD[1], Carmel Curtis MBBS[3], Marwan Hariz PhD[1,4], Ludvic Zrinzo PhD[1,2]

1 Unit of Functional Neurosurgery, UCL Institute of Neurology, Queen Square, London, UK
2 Victor Horsley Department of Neurosurgery, National Hospital for Neurology and Neurosurgery, Queen Square, London, WC1N 3BG, UK
3 Department of Clinical Microbiology, University College London Hospital, 60 Whitfield St, London, W1T 4EU, UK
4 Department of Clinical Neuroscience, Umeå University, Umeå, Sweden

Short title: Avoiding DBS IPG Infection

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Corresponding author:
Ludvic Zrinzo MD PhD FRCS
Unit of Functional Neurosurgery
Institute of Neurology,
Queen Square
London WC1N 3BG, U.K.
Phone/fax: +44 20 74191860
Email: l.zrinzo@ucl.ac.uk

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Abstract

Object:

Infection of deep brain stimulation (DBS) hardware has a significant impact on patient morbidity. Previous experience suggests that infection rates appear to be higher after implantable pulse generator (IPG) replacement surgery than after the de novo DBS procedure. Here we examine the effect of a change in practice during DBS IPG replacements in our institution.

Methods:

Starting January 2012, patient screening for meticillin resistant *Staphylococcus aureus* (MRSA) and where necessary, eradication was performed prior to elective DBS IPG change. Moreover, topical vancomycin was placed in the IPG pocket during surgery. We then prospectively examined the infection rate in patients undergoing DBS IPG replacement in our center over a 3-year period with at least 9-months follow up.

Results:

The total incidence of infection in our prospective consecutive series of 101 IPG replacement procedures was 0% with mean follow up of 24 months (SD 11). This was significantly lower than our previously published historical control group, prior to implementing the change in practice, where the infection rate for IPG replacement was 8.5% (8/94 procedures) ($p = 0.0025$).

Conclusion:

This study suggests that a change in clinical practice can significantly lower infection rates in patients undergoing DBS IPG replacement. These simple measures can

minimise unnecessary surgery, loss of benefit from chronic stimulation and costly hardware replacement, improving further the cost efficacy of DBS therapies.

Introduction

Deep Brain Stimulation (DBS) was popularised by the Grenoble group[2]~~2~~ and surpassed stereotactic ablation as the predominant treatment in functional neurosurgery at the end of the last millennium. DBS is now an established treatment for a number of movement disorders including Parkinson's disease, dystonia and tremor. This has raised interest in the possible use of DBS for severe and unremitting psychiatric disorders including obsessive compulsive disorder and depression[31]~~29~~.

Despite the surge in popularity of DBS only a small number of publications have specifically analysed the complications of DBS surgery[3,4,6,15,32,40,41]~~3,4,6,14,30,38,39~~, and even fewer have assessed interventions that can reduce the rate of adverse events[3,14,24,26,28,37,46]~~3,13,22,24,26,35,44~~.

Reported infection rates vary between centres from 0 – 22%[7,42]~~7,40~~. Our group recently published data demonstrating that infection rates after IPG replacement are significantly higher when compared to other types of DBS related surgery[32]~~30~~. Other authors have reported similar trends[3]~~3~~. However, the overall picture is far from clear, as other groups reported infection rate similar to de novo surgery[4,36]~~4,34~~.

Miller and colleagues previously reported a significant improvement in hardware related infection in all stereotactic and functional neurosurgical procedures with the use of topical antibiotics[28]~~26~~. Moreover, it is well documented that colonisation with *Staphylococcus aureus* (SA) is an independent risk factor for the development of post-surgical infection[44]~~42~~, and this risk may be as high as 33%[29]~~27~~.

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Therefore, since January 2012 we adapted our surgical procedure with the aim of reducing the rate of infection after IPG replacement surgery. Together with our local infection control team we introduced the use of MRSA screening and eradication as well as intraoperative topical vancomycin wash during IPG replacement.

The aim of this prospective study is to assess whether this change in practice made a significant impact upon infection rates after IPG replacement surgery when compared to historical controls.

Materials and Methods

Surgical reports and clinical notes were reviewed in all 171 patients (89 male, 82 female) who underwent IPG replacement surgery at the National Hospital of Neurology and Neurosurgery, Queen Square, London, from November 2002 until December 2014. Prior to January 2012 all data collected was retrospective. From January 2012 until December 2014 all patients undergoing IPG change surgery were prospectively followed up.

Baseline patient characteristics (age at surgery, gender, diagnosis, brain target) as well as details of the operation performed were collected for each patient. Before January ~~First~~1, 2012 the IPG pocket was vigorously washed with copious saline. After this date all patients underwent MRSA screening and eradication, where appropriate, prior to surgery and, at surgery the IPG pocket was instilled with a vancomycin wash prior to closure (further details below).

Patients were grouped into an historical "control" group and a "prospective" group following this change in practice. All patients had a minimum follow up time of nine months.

Information on any DBS related infection, including type, site and microbiological diagnosis was collected for all patients with infection. The definition of recorded infection is the same as in our previous study[32]~~30~~. Only infections in direct relation to the hardware were considered. Infections were defined if any of the following were present: a) clinical suspicion of an infection (i.e. redness, swelling, warmth or fluid

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surrounding any of the DBS components beyond that expected due to post-surgical inflammation, with either elevated temperature / inflammatory markers; b) purulent exudates from the suspected site of infection; c) microbiological evidence; d) skin erosion with any of the above.

The infection rate was calculated as the number of infections per patient as well as the number of infections per procedure.

Microbial Screening and Eradication Protocol

All "prospective" patients attended pre-operative assessment clinic where they underwent skin and nasal screening for MRSA colonisation. All patients who had negative colonisation results continued to surgery without eradication. Patients underwent MRSA eradication if they had either: (a) positive MRSA colonisation result, (b) unable to attend pre-operative assessment clinic, (c) historically MRSA colonisation positive or (d) delayed elective surgery in known MRSA carrier with or without previous eradication. All patients with delayed elective surgery underwent repeat MRSA screening. **Figure 1**.

See **Table 1** for details of eradication protocol.

Surgical Procedure

Replacement of IPG

Patients received 1.5g IV cefuroxime single dose or 500mg IV clarithromycin single dose in cases of penicillin allergy at induction. If they were MRSA positive Teicoplanin 6mg/kg IV was added to the primary prophylaxis. With the patient under

general or local anaesthesia, the pocket of the IPG was opened via the old scar. If the scar was "unsightly" the scar was excised together with an ellipse of skin. The old IPG was replaced with the new IPG placed in the fibrous pocket. When exchanging the old IPG for more bulky hardware (e.g.: Kinetra IPG being replaced with adaptor plus Activa PC , Medtronic, Minneapolis, MN), the new hardware was sometimes placed in a deeper pocket, formed beneath the pectoralis major muscle via a muscle splitting approach, especially when the overlying skin was deemed thin.

Before January first 2012 the pocket was washed with copious amounts of saline. After this date, vancomycin / saline wash was used (20ml of 1mg/ml vancomycin solution). The wound was closed in layers with carefully buried absorbable sutures and interrupted nylon for skin closure. The patient received three further doses of cefuroxime 750mg IV at eight hourly intervals or the appropriate alternative if penicillin allergic or MRSA positive. Dressings were not removed unless they were heavily blood stained and sutures were removed after 10-14 days. Patients were instructed to keep the wound dry until 24 hours after suture removal.

Statistical Analysis

A non-paired student t-test was used to compare the ages of patients with and without infection, between groups and the number of surgeons per operation. The infection rate between groups was compared with a Fisher exact test using a 2x2 contingency table. A p-value <0.05 was considered significant.

Results

Baseline Characteristics

In total, 171 patients underwent a total of 195 IPG replacement procedures. Of those in the historical control group, 80 patients underwent 94 IPG replacement surgeries (Age: 48±20, 48% male). This included 15 procedures (18.8%) in which patients had one or more previous IPG replacement surgeries. In the "prospective" group, 91 patients underwent 101 IPG replacement surgeries (Age 54±15, 56% male) and included 24 procedures (23.7%) in which patients had one or more previous IPG replacement surgeries. There was no significant difference in gender, primary indication for DBS surgery, brain target, or rates of diabetes between the two groups (**Table 2**).

Minimum follow up time was 9 months in both groups with mean follow up time 24±11 months in the "prospective" group and 73±26 months in the control group (p=0.0001). The number of surgeons involved was higher in the control than in the prospective group 1.8 versus 1.4 (p=0.0002). Patients in the prospective group were older and had undergone more previous IPG changes **(Table 2).**

Rate of MRSA colonisation in prospective cohort

There were no confirmed MRSA colonisations within the prospective group. However, four patients underwent MRSA eradication, three of whom had historical MRSA colonisation and one who failed to attend for MRSA screening.

Postoperative Infections

In total 8 postoperative infections occurred in 6 patients in the historical control group. This corresponds to a patient infection rate of 7.5% and a procedure infection rate of 8.5%. There were no infections in the "prospective" group. This difference is statistically significant (**See Figure 2**). Information on patients with infection is detailed in brief in **Table 3** and in more detail in our previous publication[32]~~30~~**.** The mean ± SD duration until infection in the control group was 3.1±5.8 months. None of the infections were secondary to MRSA.

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Reason for IPG Change

The most common reason for IPG change was depletion / near depletion of the IPG´s battery in both groups. Replacement of IPG after prior hardware removal because of infection was the indication in 12% of the historical control group versus 0% in the prospective group (p=0.0002). (**Table 4**).

Adverse Events

There were no adverse events noted in relation to the use of topical vancomycin wash or microbial screening/eradication.

Patients with previous DBS related infections

The historical control group contained one patient (1/80, 1.2%) with a previous DBS related infection and the prospective cohort contained 4 patients (4/91, 4.4%) who had previous infection of DBS hardware. This difference is not statistically significant.

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Special Cases

Of the 6 patients with IPG infections in the historical group, two deserve further discussion. Patient 2 underwent surgery for tardive dystonia and suffered three infections after IPG replacement surgery and four in total. The initial infection affected the IPG alone and was managed by cutting of the cables below the cranial connector site and extraction of the cut cables and IPG. The subsequent infection occurred two months later and was associated with erosion of the distal end of the cut extension cable through the skin and the cable stump was removed. Four weeks later a purulent spot over the left peri-coronal wound was noted and the patient was admitted to hospital for removal of the leads. These were all considered separate infections as they occurred at different time points all related to the most recent surgery (IPG replacement). Three and a half months later the entire system was re-implanted but the patient developed a subcutaneous infection around the IPG pocket that resulted in removal of the infected components, leaving the leads in place. Finally new cables and IPG were re-inserted 4 months later. This patient suffered from type II diabetes mellitus.

Patient 3 with severe dystonia and cachexia underwent IPG replacement due to near depletion of the battery and was discharged back to his nursing home. The patient presented to hospital seventeen months later with erosion of the IPG through the skin. On presentation no clinical signs of infection were present and an attempt was made to rescue the IPG by excising the wound margins and forming a new pocket. This was followed by development of a purulent infection.

Discussion

The use of an intra-operative vancomycin wash and microbial screening significantly reduced the rate of infection after IPG replacement surgery from a procedure infection rate of 8.5% and patient infection rate of 7.5% to 0%.

In 5/6 patients with infection in the historical control group, the causative organism of purulent infection was *Staphylococcus* species. The rate of skin colonisation of *Staphylococcus aureus* is over 70% in patients with confirmed skin and soft tissue infections[10,25]~~10,23~~. Indeed, the most common causative organism responsible for hardware infection in DBS surgery is staphylococcal species[3,4,32]~~3,4,30~~. Importantly, despite proper skin disinfectant and draping during surgery, bacteria including coagulase negative staphylococci and P*ropionibacterium acnes* will begin to colonise the skin within one hour with a marked bacterial colonisation load at two hours[12]~~12~~.

Staphylococcus aureus (SA) is a common commensal species that affects up to 2/3 of healthy individuals throughout their lifetime[22,25]~~20,23~~. The skin provides a remarkably resistant barrier to infection by colonised bacteria and this is due to a large extent to the production of antimicrobial proteins such as defensins and cathelicidins[30]~~28~~. Skin breaches during surgery allow the spread of SA within the skin and deeper tissue layers. MRSA infections can be more serious than MSSA infections due to their reduced sensitivity to commonly used antibiotics and result in worse clinical outcomes[45]~~43~~.

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Within the National Health Service in England Public Health England report that the rate of MRSA bacteraemia[16]~~15~~ and surgical site infections[9]~~ (9~~ have fallen markedly over the last decade. The reason for this is unclear but screening and subsequent isolation and eradication protocols are believed to be contributory[43]~~41~~.

Topical application of antibiotics produces far higher intra-wound concentrations than would be possible via intravenous administration alone. This is especially true in patients undergoing IPG replacement surgery where the subcutaneous fibrous pocket has a reduced blood supply. Indeed, the topical use of a variety of antibiotics has long been used effectively in treatment and prophylaxis of wound infection[5,33,35]~~5,31,33~~. Moreover, in neurosurgical shunt operations the use of local antibiotic injected directly into the shunt reduced the infection rate from 6% to 0.4% in a controlled trial of 802 shunt procedures[34]~~32~~.

Staphylococcus species are highly sensitive to vancomycin. Thus the use of a local vancomycin wash in hardware implantation surgery into subcutaneous tissue is judicious. In this study the use of a vancomycin wash in over 100 procedures with average follow up of 2 years has resulted in no infections. Importantly there were no adverse events noted from the use of vancomycin wash.

Change in Antibiotic Regimen

Bhatia and colleagues[3]~~3~~ changed the peri-operative antibiotic regimen from intravenous cefuroxime to intravenous vancomycin and gentamicin. This change reduced the overall infection rate and importantly reduced their rate of infection after IPG replacement surgery from 17.6% to 3.6%. Whilst highlighting an important trend,

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this study was under-powered and the outcome was not statistically significant. The causative organism in this original report was *Staphylococcus* species in 2/3 cases of IPG replacement. In the highly detailed review conducted by the authors, the causative organism of infection was *Staphylococcus* species in >50% cases.

Miller et al in Oregon, USA[28] ~~26~~ meticulously collected information on all stereotactic and functional hardware procedures over a 5-year period. In total 614 patients underwent a variety of procedures including DBS, spinal cord stimulator, peripheral nerve stimulator and others. All patients were given peri-operative cephalosporin or vancomycin. In the final 18 months of this study all subcutaneous pockets were irrigated with neomycin/polymyxin as opposed to saline prior to skin closure. The overall rate of infection reduced from 5.7% to 1.2% ($p<0.05$) in the group with the antibiotic washout. The causative organism of infection was *Staphylococcus* species in 82% (23/28) of cases.

In other fields of surgery and neurosurgery involving implantable hardware the use of topical vancomycin has led to marked reductions in the rate of postoperative infections. The use of a topical vancomycin powder in instrumented spinal surgery in a prospectively followed cohort led to a reduction in postoperative infection rates from 12.5% to 0%[23] ~~21~~, a finding similar to our own.

Microbial Screening and Eradication

Colonization with Staphylococcus aureus is an independent risk factor for the development post-operative surgical site infections[21, 44]

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In our study, information on MRSA carrier status was not available for all historical controls since routine screening was not conducted until January 2012. Moreover, MRSA was not cultured from any of our infected patients. Nevertheless, prior knowledge of MRSA status led to prophylactic decontamination in 3 patients within our prospective cohort. Although we suspect that the majority of the benefit seen in terms of reduced infection rates was due to the use of topical vancomycin, we cannot discount a contribution from the introduction of routine MRSA screening.

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~~In our study information on MRSA carrier status is not available for all historical controls as screening was not routinely conducted until January 2012. However, it is well documented that colonisation with *Staphylococcus* aureus is an independent risk factor for the development post operative surgical site infections(19,42) with conversion rates reported as high as 33%(27).~~

~~A recent large, single centre, prospective study examined MRSA colonisation and infection rates on 3,785 patients awaiting cardiac surgery. Twenty two out of 1,250 patients were known MRSA carriers pre operatively and eradication was successful in 21 cases. None of these patients developed a post operative surgical site infection. The remaining patients were screened preoperatively but eradication in 103 MRSA positive patients was either not started or not completed by the time of surgery. Eleven percent of these patients subsequently developed an MRSA infection. This was significantly higher than patients who had confirmed MRSA negative status pre operatively (11 vs. 0.5%, p<0.001)(19). This study emphasises the importance of meticulous screening and eradication of MRSA colonisation in reducing surgical site infections.~~

Diabetes Mellitus

It is noted in neurosurgery[11]~~11~~ and other fields of surgery[29]~~27~~ that diabetes is an independent risk factor for the development of post operative surgical infections. Importantly, in relation to this study, patients with MRSA colonisation who underwent cardiac surgery were more likely to develop post operative infection if they had a confirmed pre-operative diagnosis of diabetes[21]~~19~~.

In our patient groups the rate of diagnosed diabetes mellitus was low and similar between the two groups. This rate is similar to other published series of DBS patients[36,41]~~34,39~~. Due to the low number of diagnoses we cannot comment on its significance as a contributory factor in the development of post-operative infections. However, a number of other DBS related publications have noted that diabetes does not appear to be correlated to the development of post operative infections[20,39,41]~~18,37,39~~.

Timing of Infection / Follow up

In this study 6/8 (75%) IPG infections in the control group occurred within 2 months of surgery, 7/8 (88%) occurred within 6 months and all infections occurred within 17 months of surgery. The mean follow up of 24 months and minimum follow up of 9 months in the "prospective" group may thus be considered adequate to determine the rate of post-procedural infections. Therefore, it is unlikely that the (inevitably) shorter duration of follow up in the second group contributed to the lower rate of infection in any meaningful way. Indeed, other studies support the notion that the majority of post-surgical infections (roughly 80%) occur within the first few months of surgery

with a smaller proportion, often not directly related to surgery, occurring at a later stage, usually up to two years post-procedure[3,4,32]~~3,4,30~~.

Number of surgeons

The number of surgeons was higher in the control group on average by 0.4 surgeons over 101 procedures. This might have contributed to the higher infection rate within the control group, although this is uncertain. Other groups have noted that the number of individuals present in the operating room is related to a higher infection rate [39]~~37~~. However, at our institution the consultant (attending) surgeon listed in the operative record and supervising the procedure does not always scrub for the procedure. Therefore, these numbers must be interpreted with caution and it is not clear whether the number of scrubbed surgeons is a significant contributing factor.

Number of previous IPG replacement surgeries

We postulated in our previous publication that the number of IPG replacement surgeries might be an independent risk factor for infection[32]~~30~~. Our reasoning was two-fold: that the fibrous pocket around the IPG does not provide an adequate inflammatory response to infection and the likely reduced penetrance of prophylactic intravenous antibiotics increases the likelihood of an infection. Indeed, the number of pacemaker changes is a risk factor for infection when compared to de novo implantation in cardiac surgery[1,8,17,18]~~1,8,16,17~~. Furthermore, in hip replacement surgery the rate of infection is 18% higher after repeat revision when compared to de novo surgery[27]~~25~~. A recent publication has confirmed an increasing infection rate in multiple DBS IPG changes[38]~~36~~.

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In our prospective group, 15% of all surgeries occurred in patients who had two or more previous IPG replacements and almost a quarter of all patients had at least one previous IPG change. This is to be compared to 4% (p=0.048) and 16% (p=NS) of patients in our control group respectively. Although the number of IPG changes is an independent risk factor for infection, our protocol appears to significantly negate this risk in IPG replacement surgery.

Study Limitations

Comparison of a prospective cohort with a historical control group may give rise to potential confounds that contributed to the difference in infection rates. Nevertheless, our DBS service has always been alert to the importance of minimizing infection. No changes were made to the surgical procedure in the prospective group other than the addition of topical vancomycin wash. Surgical learning curves may also lead to higher early complication rates[13]. However, a surgical learning curve may not be present when a relatively simple procedure is performed by an experienced surgeon[19]. Indeed, the majority of infections in the historical control group did not occur in the early years of our DBS service[32].

Moreover, the prospective group was older with more repeat IPG changes, both independent risk factors for infection. This suggests that a greater baseline risk for the prospective group was reversed by using topical vancomycin wash

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Conclusions

The use of topical vancomycin has significantly reduced the rate of infection after IPG replacement surgery. MRSA screening and eradication may also have contributed to the reduced infection rate. No adverse events were noted and our protocol appears to have negated the increased risk of infection associated with multiple IPG changes. These simple measures prevented unnecessary surgery, loss of benefit from chronic stimulation and costly hardware replacement, improving further the cost efficacy of DBS therapies.

~~In summary, MRSA screening and eradication, and the use of topical vancomycin have significantly reduced the rate of infection after IPG replacement surgery. Importantly, no adverse events were noted, and meticulous adherence to our protocol appears to have negated the increased risk of infection associated with multiple IPG changes in our prospective group. These simple measures prevented unnecessary surgery, loss of benefit from chronic stimulation and costly hardware replacement, improving further the cost efficacy of DBS therapies.~~

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Disclosures

LZ and MH have occasionally received honoraria and travel expenses for speaking at meetings from Medtronic and St Jude Medical.

Figure Legends

FIG 1: New Protocol

FIG 2: Percentage of patients with infection

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Figure 1. New Protocol

Figure 1

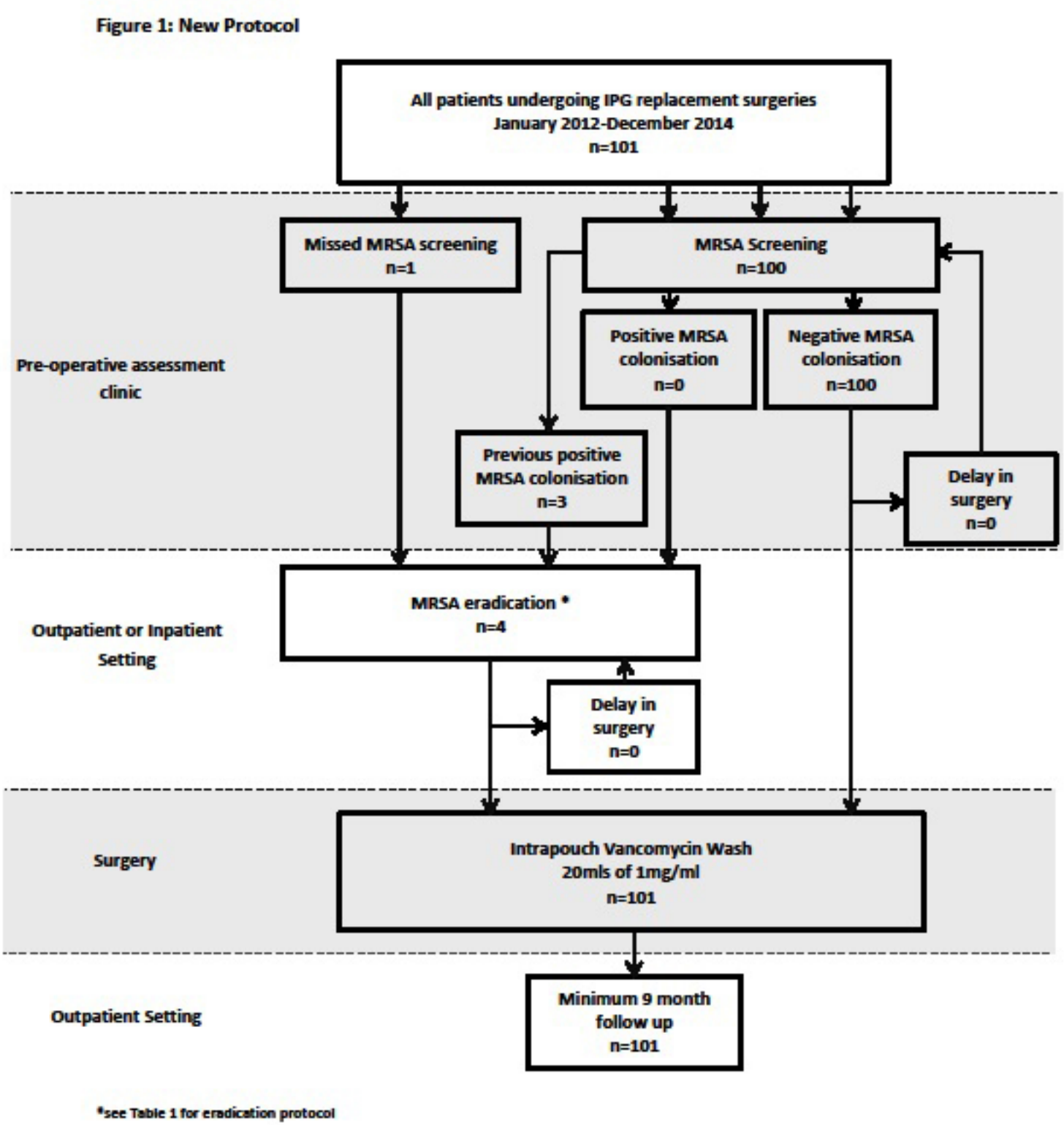
Figure 1: New Protocol
All patients undergoing IPG replacement surgeries
January 2012-December 2014
n=101
Missed MRSA screening
n=1
MRSA Screening
n=100
Positive MRSA colonisation
n=0
Negative MRSA colonisation
n=100
Pre-operative assessment clinic
Previous positive MRSA colonisation
n=3
Delay in surgery
n=0
MRSA eradication *
n=4
Outpatient or Inpatient Setting
Delay in surgery
n=0
Surgery
Intrapouch Vancomycin Wash
20mls of 1mg/ml
n=101
Minimum 9 month follow up
n=101
Outpatient Setting
*see Table 1 for eradication protocol

Figure 2. Percentage of Patients with Infection

Figure 2

Figure 2: Percentage of patients with infection

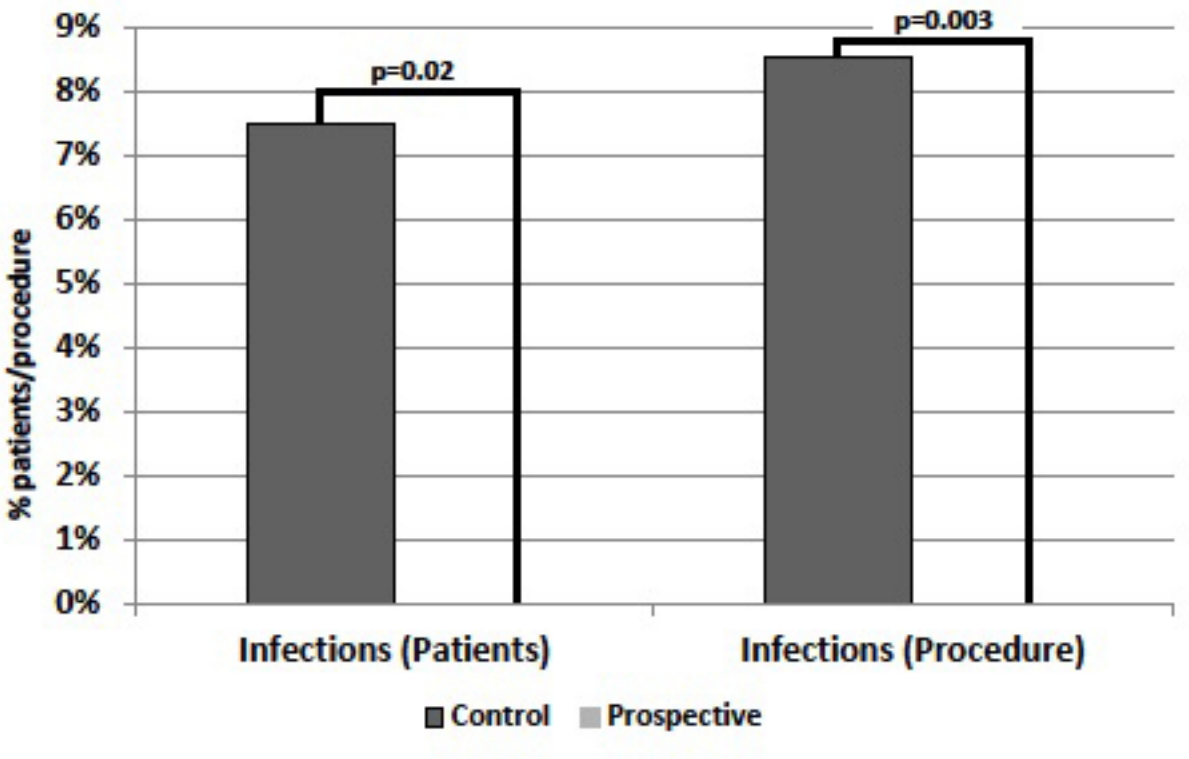

Table 1: Eradication Protocol

Type of Wash	Anti-Microbial	Frequency	Length of time
Body Wash	Chlorhexadine Gluconate 4%*	Once per day	6 days
Hair Wash	Chlorhexadine Gluconate 4%*	Every other day	5 days
Nasal	Mupirocin 2%	Three times per day	5 days

Protocol					
Day 1	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Surgery**
Body Wash Hair Wash Nasal	Body Wash Nasal	Body Wash Hair Wash Nasal	Body Wash Nasal	Body Wash Hair Wash Nasal	Body Wash

*Octenisan® (Schülke, Norderstedt, Germany) used as a substitute if Chlorhexadine Gluconate 4% contraindicated

Table 2: Baseline Characteristics

	Control	Prospective	p
N(patients)	80	91	-
N(procedures)	94	101	-
Age (SD)	48(20)	54(15)	0.018*
Male (%)	48%	56%	0.25
F/u (months) (SD)	73 (26)	24 (11)	0.0001*
Diabetes Mellitus % (number)	1% (1/80)	2% (2/91)	0.80
N (surgeons) (SD)	1.8(0.7)	1.4(0.6)	0.0002*
PD (%)	54%	45%	0.23
Dystonia (%)	42%	42%	1.0
Other Diagnosis (%)	3%	14%	0.02*
STN (%)	48%	37%	0.17
GPi (%)	49%	57%	0.29
Other Targets (%)	4%	6%	0.73
Patients with previous infections (%)	1.2%	4.4%	0.37
N (≥1 previous IPG change)	15	24	0.58
N (≥2 previous IPG change)	4	15	0.048*

***Statistically significant**

PD – Parkinson's Disease, STN – Subthalamic Nucleus, GPi – Globus Pallidus Interna, N – Number, IPG – Implantable pulse generator, F/u – follow up

Table 3: Characteristics of patients in the historical group who suffered infection following IPG replacement.

Patient	Sex	Age	Diagnosis	Target	Side	Time to Infection	Hardware Involved	Type of Infection	Culture Result	Hardware Removed
1	M	61	PD	GPi	B	2 weeks	IPG	Suppurative	S. aureus	Yes
2	M	63	DT	GPi	B	3 days	IPG	Suppurative	Coagulase negative staphylococcus	Yes
	M	64	DT	GPi	B	2 months	Cable	Erosion through skin		Yes
	M	64	DT	GPi	B	4 months	Electrode (scalp)	Purulent spot around left frontal incision		Yes
3	M	36	DT	GPi	B	17 months	IPG	Erosion of IPG through skin	C. albicans	Yes
4	M	40	DT	GPi	B	9 days	IPG, Cable	Suppurative	Electrode tip: S. epidermidis	Yes
5	M	43	DT	GPi	B	3 days	Cable, electrode (scalp and brain)	Suppurative, Cerebral Abscess	S. aureus	Yes
6	M	43	DT	GPi	B	1 month	IPG	Suppurative	S. aureus	Yes

M: Male. PD: Parkinson's Disease. DT: Dystonia. GPi: Globus Pallidum Internus. B: Bilateral, IPG: Implantable Pulse Generator

Table 4: Reasons for IPG change

	Control	Prospective	p
Depleted battery	80	93	0.17
Infection	11	0	0.0002
Malfunction	2	4	0.7
Discomfort	1	2	1.0
Other	0	2*	0.5

*Other includes one patient that required more complex programming and a second patient who had a poor response to a new IPG so was changed back to the old model.