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# Title of the subject of memory

Evaluation of the "Spine Sage" model who predicts the surgical site infection risk after spinal surgery : a retrospective case-control analysis of 50 patients operated for posterior lumbar fusion after degenerative spine disease.

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**Abstract :**

**BACKGROUND CONTEXT:** Surgical site infections (SSI) is one of the most common complications in spinal surgery which potentially leads to higher morbidity, mortality, extended length of hospital stays, and increased health care costs. Currently, there is a validated risk stratification model, the Spine Sage model that specifically predicts the likelihood of surgical site infection after spinal surgery requiring return to the operating room for surgical debridement. The value of this model is that it gives the user in percentage the absolute probability of developing a post-operative SSI depending on the surgical invasiveness and patient's comorbidities. Patients are much more likely to understand an absolute percentage, rather than relative risk and confidence interval values. A model like this is of paramount importance to counsel patients and foresee the safety of a spinal procedure.

**PURPOSE:** To evaluate the ability and discriminatory power of the "Spine Sage" model to predict the risk of surgical site infection requiring surgical debridement after posterior lumbar fusion.

**OUTCOME:** See if patients who have had a surgical site infection and have had surgical debridement were predicted by the "Spine Sage " model and if so, from what percentage is the patient really at very high risk to make an infection of the operative site requiring a return to the operating room.

**METHODS:** We carried out a retrospective case-control study, by the use of the computerized files patients of the HUG neurosurgery department to collect information concerning the risk of infection of 50 patients operated on between 2011 and 2014 for posterior lumbar fusion because of degenerative lumbar pathologies. Of these 50 patients, N=7(14%) were detected with postoperative surgical site infection (*SSI group*) and N=43(86%) without postoperative surgical site infection (non-*SSI group*). The part of Spine Sage model predicting the chance to return to operating room for a SSI debridement was retrospectively applied to the whole cohort. The discriminatory power of Spine Sage model to predict SSI requiring a new operation was then calculated and compared between the two groups. The risk factors required for calculating the infectious risk by the "Spine Sage" model were extracted and were entered into the website www.spinesage.com in order to calculate for each patient the Spine sage value. The data is summarized by group (SSI group vs non-SSI group) using the mean (SD) for continuous variables or median (range) when the normality assumption was violated. For categorical variables, the summary is given by numbers and percentages. Identification of variables associated with the SSI group is performed by univariate logistic regression.

**RESULTS:** The univariate logistic regression showed that the risk of infection increases linearly with the Spine Sage score. The gain of one point of Spine Sage increases the risk of infection by 25% and this increase is almost significant p value = 0.052. The discriminatory power of the spine sage score including all data (N = 50) measured using the area under ROC curve was of 0.67 which is considered like a not very good discriminating ability of the Spine Sage model to predict SSI.

**CONCLUSION:** There are currently very few models that predict the risk of SSI requiring a return to the operating room for debridement and the Spine Sage model that we evaluated in our study is not very prone to predicting it and this probably because the small size of our sample and its homogeneity in terms of pathologies.
**KEY WORDS:** surgical site infection, Spine Sage model, risk factors of surgical site infection, degenerative spine disease.

## I-INTRODUCTION

### I.1- Generality on lumbar spine degenerative diseases

Degenerative spinal disease is one of the most common disorders, affecting adults at every age, which means it is an important medical and social problem (1). Aging and general wear associated with the body's natural processes are the main causes of the degenerative states of the spine (2). A major feature of degenerative spine disease is that it involves the entire disco-vertebral unit, usually at several levels. A disco-vertebral unit is the complex of anatomical structures comprising a single segment of the spine, it consists of the intervertebral disc, adjacent parts of the vertebral bodies, facet joints, ligamenta flava and longitudinal ligaments at a given level. All of these components may be affected by degenerative disease of the spine to varying degrees (1). The spine is a narrow column filled with sensitive nerve tissue, any change in the structural integrity or placement of the disks can potentially impinge on adjacent spinal nerves, which is often the underlying cause of the painful symptoms of degenerative spine (3).

There are many types of degenerative spine disease : (2)

- Spinal osteoarthritis : this condition involves the breakdown of cartilage located on the spinal facet joints. When osteoarthritis occurs, cartilage wears away, allowing bone-on-bone contact to occur within the joint. This can cause inflammation, the formation of bone spurs and nerve irritation.
- Degenerative disc disease: this condition describes the breakdown of intervertebral discs. When we grow older, the intervertebral discs dehydrate and the proteins that keep them healthy break down. As the discs deteriorate, they become less effective at supporting the vertebrae. This can cause the vertebrae to become slightly displaced and put pressure on the nerve roots that travel in between the vertebrae, or press on the spinal cord itself.
- Herniated discs : refers to an intervertebral disc that has ruptured, allowing the inner gel-like disc material to seep into the spinal canal through a tear in the disc wall. This condition can be painful if the extruded disc material irritates the spinal nerves.
- Spondylolisthesis : is a condition indicated by the presence of vertebral misalignment, one of the vertebral bodies slides out of its normal position. This condition is described in degrees of severity, with Grade 1 spondylolisthesis representing 0 to 25 percent slippage and Grade 4 spondylolisthesis indicating 75 to 100 percent vertebral slippage.
- Degenerative scoliosis : it causes a side-to-side curvature of the spine, which can result in symptoms including a hunched posture or a change in gait.
- Spinal stenosis : describes the narrowing of the spinal canal. When the canal space becomes constricted, the spinal cord and other nerve structures can be irritated. Common causes of spinal stenosis include the presence of herniated disc material, bone spurs and other tissue.
- Foraminal stenosis : describes the narrowing of the passageways through which nerve roots enter and exit the spinal canal, if the space becomes so narrowed that the nerves are irritated, a variety of painful symptoms may develop (2).
- A synovial cyst is a fluid-filled sac develop as a result of degeneration in the facet joint in the lumbar spine, it is most common in patients older than 65 years old. The fluid-filled sac creates pressure inside the spinal canal, which can give a patient all the symptoms of stenosis of the spine (4).

When deterioration of the spine progresses to the point where symptoms interfere with regular activity, treatment may be warranted (3).

In all cases of degenerative disease of the spine, initial management is medical. In general, surgical intervention is only considered when the patient has had a complete medical treatment without improvement of the symptoms. The purpose of the operation is to relieve the compression of the nervous elements. Depending on the importance of bone resection performed or in some situations, such as the: presence of a vertebrae sliding compared to another preoperatively (spondylolisthesis), it may be necessary to fuse two or more vertebrae. This procedure, in surgical language, is called arthrodesis or spondylodesis (5).

### I.2- Lumbar spondylodesis or fusion

Lumbar fusion is a surgical procedure in which two or more vertebrae are fused together (6). The principal indication for lumbar interbody fusion surgery is the instability related pain. Therefore, lumbar fusion has been described as a treatment of symptomatic spondylolisthesis, degenerative scoliosis, and spinal stenosis associated with instability (7). This procedure is performed using anterior (ALIF Anterior Lumbar Interbody Fusion), lateral (LLIF lateral lumbar interbody fusion), transforaminal (TLIF Transforaminal Lumbar Interbody Fusion) and posterior approache (PLIF Posterior Lumbar Interbody Fusion) (8,9), (Fig 1).

In PLIF fusion technique, a incision is made in the patient's back and the spinal muscles are retracted (or separated) to allow access to the vertebral disc. The surgeon then carefully removes the lamina (laminectomy) to be able to see and access the nerve roots. The facet joints, which lie directly over the nerve roots, may be trimmed to allow more room for the nerve roots. The surgeon then removes the affected disc and surrounding tissue and prepares bone surfaces of adjacent vertebrae for fusion. Once the disc space is prepared, a cage (a biomechanical spacer implant) is inserted into the disc space to promote fusion between the vertebrae. Additional instrumentation (such as rods or screws) will also be used at this time to further stabilize the spine (6,7,10).

The TLIF technique involves approaching the spine in a similar manner as the PLIF approach but more from the side of the spinal canal through a midline incision in the patient's back. The spinal canal is entered via a unilateral laminectomy and inferior facetectomy, which facilitates bone graft placement. After adequate decompression of the neural elements has been performed, pedicle screws are placed in the standard fashion. The disc space can be gradually distracted by using the pedicle screws or an intralaminar spreading device. Once the graft has been placed within the interbody space, pedicle screws are then attached to lordotic rod and carefully compressed to restore lumbar lordosis (7). Compared to a traditional PLIF technique, the TLIF approach preserves ligamentous structures which are instrumental to restoring biomechanical stability of the segment and adjacent structures (6,7,10).

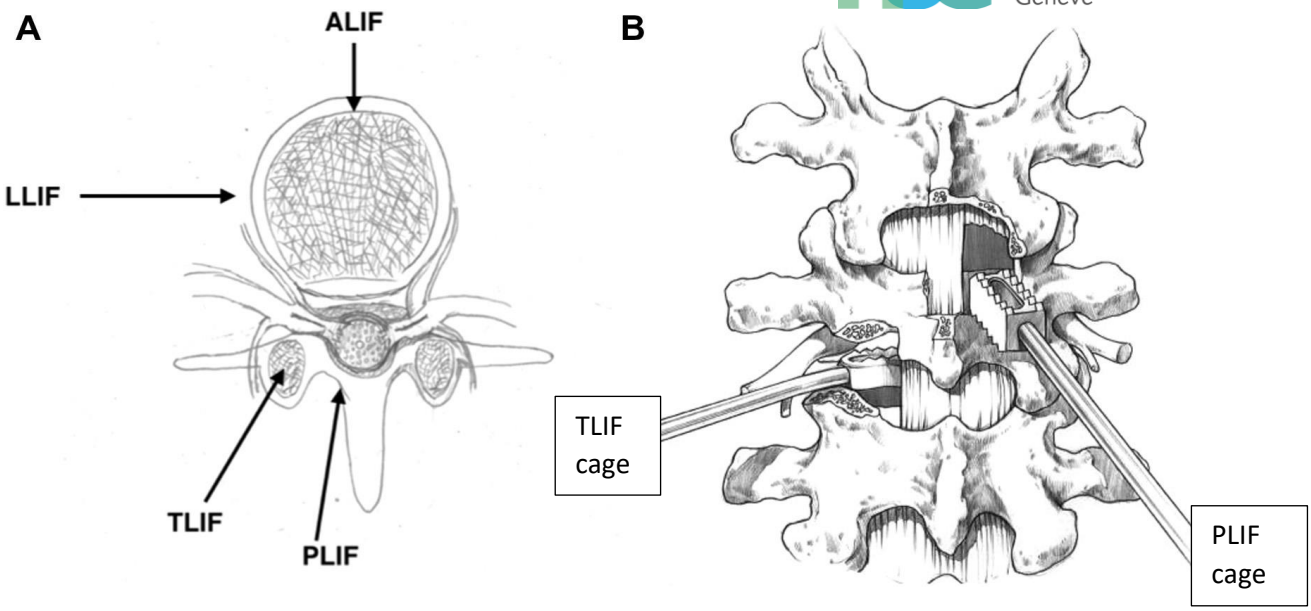



Fig 1 : Surgical approaches for the column fusion procedure. (A) The four main approaches to intervertebral fusion are represented here schematically starting with the anterior (ALIF), lateral (LLIF), transforaminal (TLIF) and posterior (PLIF). (B) : Schematic representation of lumbar spine demonstrating the angle of interbody graft insertion for the PLIF procedure (*top, medial*) and TLIF procedure (*bottom, lateral*) (7).

**Source :** Cole CD, McCall TD, Schmidt MH, Dailey AT. Comparison of low back fusion techniques: transforaminal lumbar interbody fusion (TLIF) or posterior lumbar interbody fusion (PLIF) approaches. Curr Rev Musculoskelet Med. Avril 2009;2(2):118-26.

The risks of the procedure are the risks inherent in any surgical procedure (anesthetic risk related to positioning on the table, phlebitis, etc.) and the risks specific to fusion surgery, such as implants misplacement or failure, non-union, hemorrhage, CSF (cerebro-spinal fluid) leak, etc. Infection may occur despite all procedures used to reduice the risk for infections in the operating room. These are often superficial skin infections that are regulated by appropriate care. A deep infection is more serious because it develops around the metallic material put in place and requires a fast management associating surgical revision and washing of the surgical wound under general anesthesia and antibiotherapy adapted following the samplings carried out and put in culture for know the incriminated germs (11).

### I.3- Surgical site infection (SSI) after spine surgery

#### I.3.a- Definition and incidence

Superficial SSI : occurs within 30 days after the operation, involves only the skin or subcutaneous tissue and at least 1 of the following:

- Purulent drainage (culture documentation not required)

- Organisms isolated from fluid/tissue of superficial incision

- At least 1 sign of inflammation (eg, pain or tenderness, induration, erythema, local warmth of the wound)

- Wound is deliberately opened by the surgeon

- Surgeon or attending physician declares the wound infected.

Deep SSI : occurs within 30 days of operation or within 1 year if an implant is present. It involves deep soft tissues (eg, fascia and/or muscle) of the incision and At least 1 of the following:

- Purulent drainage from the deep incision but without organ/space involvement

- Fascial dehiscence or fascia is deliberately separated by the surgeon due to signs of inflammation

- Deep abscess is identified by direct examination or during reoperation, by histopathology, or by radiologic examination

- Surgeon or attending physician declares that deep incisional infection is present (12).

Surgical site infections (SSI) is one of the most common complications after spinal surgery (13,14). They are a hospital-acquired infection of the skin, soft tissue, or bone, (13) which leads to higher morbidity, mortality, extended length of hospital stays and increased health care costs (13,14,15,16,17).

Some studies reported that incidence for SSI after spinal surgery was between 0.7% and 12% depending on the nature of the procedure (Diskectomy is associated with less than a 1% risk of infection; spinal fusion without instrumentation is associated with a 1%-5% risk; and fusion with instrumentation may be associated with a risk of 6% or more) (18), diagnosis, Preoperative comorbidities and risk factors of patient (13,14,15,16,19,20,21,22,23,24).

The majority of infections occurres during the early postoperative period (less than 3 months)(19).

The literature demonstrates an increased risk of postoperative infections associated with advanced age (Age >60 years), smoking, diabetes mellitus, previous surgical infection, multiple fusion segments, obesity, alcohol, surgical invasiveness index of >21 (21), immunosuppression, increased surgical time, blood loss, prior spine surgery, ASA class ((American Society of Anesthesiologists), ischemic heart disease, arrhythmia, chronic liver disease, autoimmune disease and length of hospital stay were preoperative risk factors for SSI (13,14,16,17,18,19,22) among patients undergoing instrumented lumbar fusion for degenerative spine disease (22).

Infections were primarily monomicrobial, Staphylococcus aureus was the most frequent organism cultured (more than 50% of the cases) (18,19,20). Other recurring organisms were Staphylococcus epidermis, Peptococcus, Enterobacter cloacae, Enterococcus faecalis, Pseudomonas spp, Proteus mirabilis and Bacteroides and many patients have multiple organisms (12,18).

According to SWISSNOSO 2017 (National Center for Infection Control), the rate of the surgical site infection after spine surgery in the neurosurgical department at Geneva University Hospitals (HUG) was 3.6% from October 2014 to September 2015, and 3.5% from October 2015 to September 2016 (Fig 2).

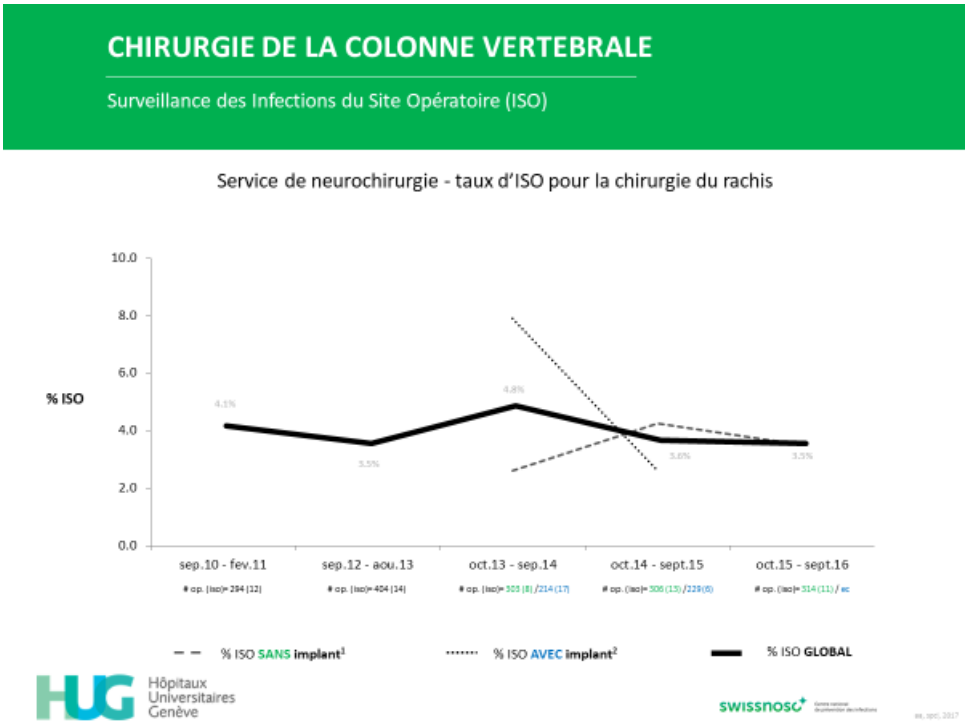



Fig 2 : SWISSNOSO 2017 : the rate of surgical site infection after spine surgery in the neurosurgery department at Geneva University Hospitals from october 2014 to september 2016.

**I.3.b- Spine Sage model (Fig 3) :**

Frequently, the magnitude of the risk of infection of the operative site is expressed in epidemiological terms of probabilities, relative risk values or odds ratios (OR). Although these values are statistically and scientifically valid, they may be difficult to translate to the patient during surgical options counseling. Knowing if our patient is at high risk for surgical site infections is helpful in terms of preoperative counseling, perioperative follow-up, and improved safety of spine surgery (15).

Currently, there is a validated risk stratification model that specifically predicts the risk of post-spine surgical site infection, the Spine Sage model, developed from the Department of Orthopedic Surgery and Sports Medicine at the University of Washington Medical Center (15). It predicts the likelihood of surgical site infection after spinal surgery requiring return to the operating room for surgical debridement. The value of this model is that it gives the user in percentage the absolute probability of developing a post-operative surgical site infection of the spine depending on the invasive profile of the patient's surgery and comorbidities. Patients are much more likely to understand an absolute percentage, rather than relative risk and confidence interval values. A model like this is of paramount importance to counsel patients and improve the safety of spine surgery (15).

To validate this model, a preliminary study was conducted in Washington (15,25). They performed a multivariate analysis of 1532 patients to assess the risk of surgical site infection after spinal surgery. This on the basis of a large prospective surgical registry. Risk factors examined: age, sex, smoking, alcohol consumption, diabetes, body mass index, surgical approach (posterior, anterior, combined),

revision surgery, surgical region (cervical, thoracic, lumbosacral), diagnosis ( degenerative, traumatic, neoplastic), infection or other), and the invasive aspect of surgery. This shows an incidence of 2.15% of surgical site infections requiring debridement per year for patients undergoing spinal surgery. To facilitate the use of this model, they have created a website (spinesage.com) where users can enter patient data to determine the likelihood of surgical site infection following spinal surgery requiring surgical debridement (15,26). Access to spinesage.com is free and unpaid.

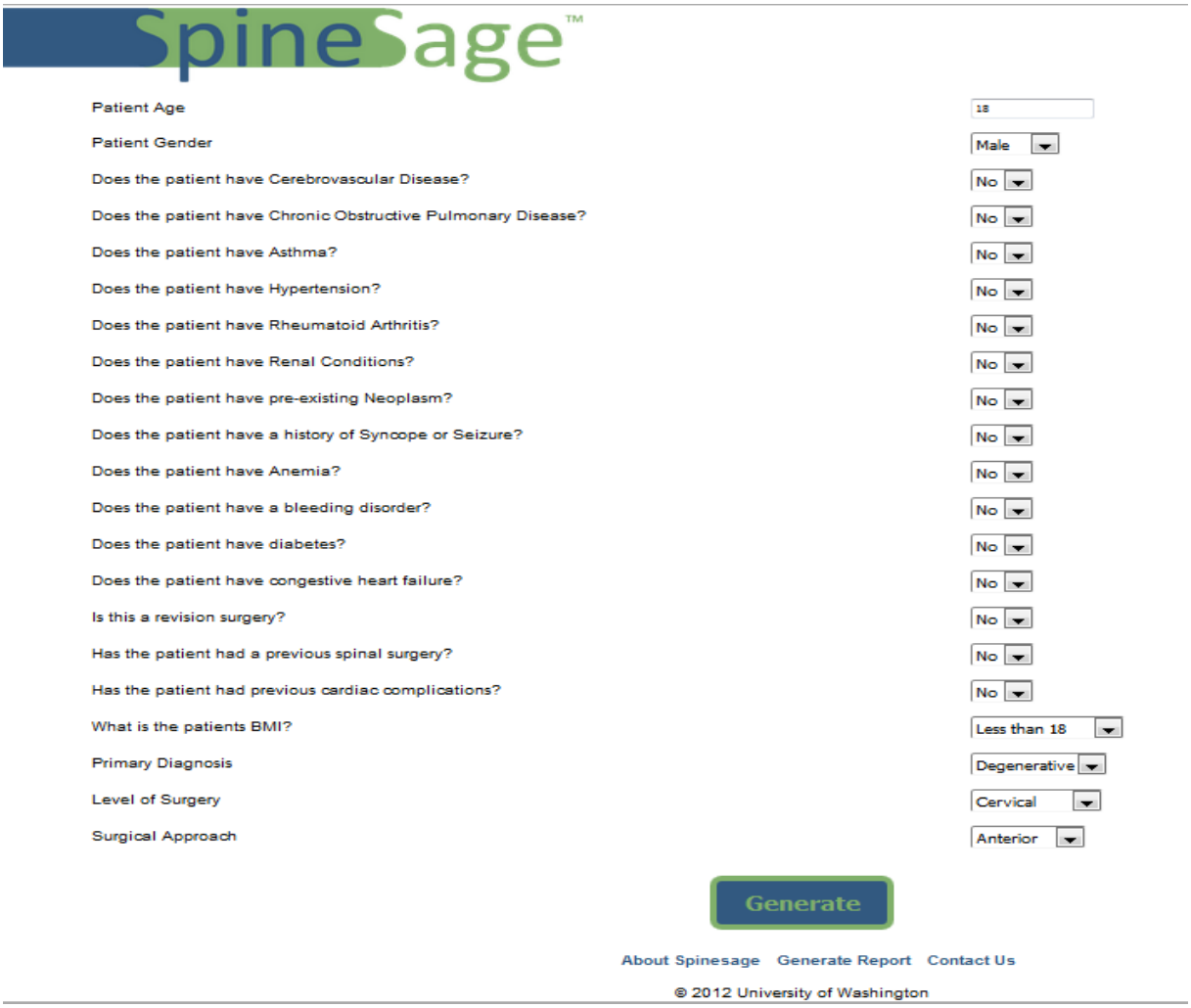



Fig 3 : Spine Sage model

**Source :** SpineSage [Internet]. [cité 28 nov 2017]. Disponible sur: http://depts.washington.edu/spinersk/

**<u>The aim of this study is</u>**

To evaluate the ability and discriminatory power of the "Spine Sage" model to predict the risk of surgical site infection requiring surgical debridement after posterior lumbar fusion.

## I- METHODS

**II.1- Patient population :**

We carried out a retrospective case-control study, with the authorization of the Geneva Ethics Commission (2016-00981) for the use of the computerized files of patients of the HUG neurosurgery department to collect information concerning the risk of infection.

N=50 patients operated on between 2011 and 2014 for posterior lumbar fusion because of degenerative lumbar pathologies were included in this retrospective study. Patients having history of cancer or infection, or operated on for other than degenerative pathologies were excluded from the study.

Of these 50 patients, N=7(14%) were detected with postoperative surgical site infection (**SSI group**) and N=43(86%) without postopérative surgical site infection (**non-SSI group**). The part of Spine Sage model predicting the chance to return to operating room for a SSI debridement was retrospectively applied to the whole cohort. The discriminatory power of Spine Sage model to predict SSI requiring a new operation was then calculated and compared between the two groups.

**II.3- Data collection :**

From the DRG codes and help from the HUG Coding Service, we obtained the list of patients who had used lumbar fusion surgery from 2011 to 2014.

The data collection was carried out on the computer platform dedicated to the archiving of medical records of HUG patients, namely "DPI".

We found 7 patients who underwent surgical debridement for post-spondylodesis surgical site infection of the lumbar spine between 2011 and 2014 at HUG and 43 control patients who did not have surgical site infection requiring surgical debridement. We assigned a code to each patient.

**II.4- Variables**

The risk factors required for calculating the infectious risk by the "Spine Sage" model were extracted in an excel table. These risk factors are: age (range: 18 to 98 years), sex (male or female), history of cerebrovascular disease (stroke or transient ischemic attack), chronic obstructive pulmonary disease, asthma, high blood pressure (blood pressure> 140/90 mmHg), rheumatoid arthritis, kidney disease, syncope or epilepsy, cancer, anemia, coagulation problem, diabetes, congestive heart failure, surgical revision, history of spinal surgery, history of cardiac complications, body mass index, primary diagnosis (degenerative pathology of the spine: spondylolisthesis, narrow lumbar canal, discopathy, foraminal stenosis, arthrosynovial cyst), level of surgery (lumbar), and surgical approach (posterior) (fig 3).

These collected data were entered into the website www.spinesage.com (for the majority of these risk factors we had to fill in yes or no) in order to calculate for each patient the percentage of risk he would have had preoperatively surgical site infection requiring wound debridement after posterior fusion.

The percentage of infection corresponding to each patient is a function of the surgical invasiveness index. Thus, for each patient we calculated the index of surgical invasiveness who is a validated scale that takes into account the number of decompressed, merged, or instrumented levels, both posterior and prior.

It ranges from 0 to 48, the higher score indicates greater invasiveness and higher risk of infection. The index is the sum of six items: anterior decompression (ad), anterior fusion (Af), anterior instrumentation (ai), posterior decompression (Pd), posterior fusion (pf), and posterior instrumentation (pi) (25).

Other additional data collected include ASA score (American Society of Anesthesiologists), fixed level number, instrumented level number, length of hospital stay, and maximum follow-up.

### II.5- The outcome

The goal of this study is to see if patients who have had a SSI and have had surgical debridement were predicted by the "Spine Sage " model and if so, from what percentage is the patient really at very high risk to make an infection of the operative site requiring a return to the operating room.

Compare a binary variable comprising a group of patients who had a surgical site infection requiring surgical debridement (SSI group) against a group that did not have a surgical site infection (Non-SSI group), which we will put in contact with a continuous independent variable that is the percentage of infectious risk post-spine surgery calculate according to the "Spine Sage" model.

### II.6- Statistical Method:

Statistical analyzes is performed with the STATA software (StataCorp 2015. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP). The data is summarized by group (SSI group vs non-SSI group) using the mean (sd) for continuous variables or meadian (range) when the normality assumption was violated. For categorical variables, the summary is given by numbers and percentages. Identification of variables associated with the SSI group is performed by univariate logistic regression model. The strength of the association between each explanatory variable and the SSI group is measured with the OR (Odds-Ratio) and its significance with the calculated p-value. A p-value <0.05 is indicative of a statistically significant association. Given the insufficiency of the sample size no multivariable analysis was performed.

In addition the prediction performance of the "Spine Sage" score to predicts the risk of surgical site infection was analyzed using univariate logistic regression model where the "Spine Sage" score was introduced alone in the model. The area under roc curve and the best cutoff for an optimal sensitivity and specificity was identified.

## II- RESULTS

### III.1- Patient demographics (table 1)

A total of 50 patients who underwent posterior lumbar spinal fusion were included in this study, mostly women N=34 (68%) and males N=16 males (32%), with a mean age of 60.22± 14.11 years

(range= 27–82), and a mean body mass index (BMI) of 26,88± 4.32 kg/m2 (range= 20-43). N=16 (32%, range=1-3) of the patients underwent at least one previous spinal surgery at the same site.

The mean surgical invasiveness score was 10.36± 2.72 (range=9–22) and the mean number of fixed level was 1.3± 0.68 (range=1-4). Most of the operations were performed using a PLIF approach N=29 (58%), followed by a TLIF approach N=21 (42%). The mean follow-up was 10.08± 9.45 months (range=1–42), and mean duration of postoperative hospital stay was 11.88± 8.95 days (range=4-41). The indication to surgery was: spondylolisthesis in N=42 cases (84%), lumbar spinal stenosis in N=24 cases (48%), discopathy in N=12 cases (24%) foraminal stenosis in N=9 cases (18%), and synovial cyst in N=2 cases (4%).

**III.2- Comparison of the variables between the 2 groups (with versus without SSI) and univariate logistic analysis (Table 1-2) :**

N=7 (14%) were detected with postoperative surgical site infection (**SSI group**) and N=43 (86%) without postoperative surgical site infection (**non-SSI group**). Patients, in SSI group included N=5 (71.43%) males and N=2 (28.57%) females. Both groups were homogeneous in term of age, BMI, number of previous surgeries and mean follow-up. Indeed, in SSI group, the mean patient age was 59.57 ± 12.37 years (range=35-70) versus 60.33± 14.50 years (range=27-82) for non-SSI group (OR=0.99, P=0.89). The mean BMI was 28.83± 7.14 kg/m2 in SSI group versus 26.57± 3.67 kg/m2 for non-SSI group (OR=1.18, P=0.76). The mean number of previous spine surgery in SSI group was 1± 1 (range=0-2) versus 0.53± 0.96 (range=0-3) in non-SSI group (OR=1.55, P=0.25), and the mean follow-up was 15.29± 11.47 months (range=6-36) in SSI group versus 9.23 ± 8.96 months (range=1-42) (OR=1.05, P=0.13).

On the other side, the mean surgical invasiveness score was 13.43±4.96 (range=9-22) in the SSI group versus 9.86 ± 1.81 (range=9-15) in non SSI group (OR=1.45, P=0.013) and number of fixed level was on average 2.14±1.35 (range=1-4) in SSI group against 1.16±0.37 (range=1-2) in non-SSI group (OR=5.28,P=0.017).

Once the Spine Sage model calculated, the mean percentage spine sage score was 9.25± 3.33 (range=5.34-14.11) in SSI group versus 6.79± 2.68 (range=5.27-15.79) in non-SSI group with (OR=1.25, P=0.052) meaning that an increase of one point of spine sage increases the risk of infection by 25%. In 5 of 7 patients, SSI occurred during the first postoperative week, they were deep in 4 out of 7 patients and polymicrobial in 3 of 7 patients.

The univariable logistic regression analysis revealed that gender was significantly associated to the infection. Men are more likely to have infection (OR=7.27, P=0.03), smoking (OR=7.87, P=0.09), revision surgery ((OR=7.27, P=0.03), increased of surgical invasiveness index (OR=1.45, P=0.013) (Fig 4), increased number of fixed level (OR=5.28, P = 0.017) (Fig 5), and increased number of instrumented level (OR=5.61, P=0.03) were found to be statistically significant risk factors for SSI. SSI significantly increases duration of postoperative hospital stay (OR=1.36, P=0.003) (Fig 6), whereas diagnostic of spondylolisthesis decreased the risk of SSI (OR=0.03, P=0.03). When passing from class 2 (range=6-10) to class 3 (range=11-15) of surgical invasiveness index, risk of SSI increases of 3 times (OR=3.43, P=0.22).

Previous spine surgery (OR=3.44, P=0.5), history of diabetes mellitus (OR=5.33, P=0.10), TLIF approach (OR=2.04, P=0.39), renal disease (OR=2.22, P=0.51), history of Chronic Obstructive Pulmonary Disease (OR=2.22, P=0.51) were associated with increased risk of SSI that required a return to the operating room, but the increase in the observe risk was not statistically significant. Age was not significantly associated with infection risk (OR=0.99, P=0.89) (Fig 7).

**III.3- Discriminatory power of the Spine Sage model to predict SSI :**

The univariate logistic regression showed that the risk of infection increases linearly with the Spine Sage score (Fig 8). The gain of one point of Spine Sage increases the risk of infection by 25% and this increase is almost significant p value = 0.052, (Table 1).

Fig 9 shows that the median of Spine Sage percentage is about 9.5% in the SSI group versus about 5.5% in the non-SSI group (the average percentage of Spine Sage is 6.79% (± 2.68) in the non-SSI group versus 9.25% (± 3.33) in the SSI group), but there is an overlapping graph area where we can not discriminate SSI patients from those without SSI because some patients in the non-SSI group have a percentage of Spine Sage greater than 14%.

The discriminatory power of the spine sage score including all data (N = 50) measured using the area under ROC curve was of 0.67 which is considered like a not very good discriminating ability of the Spine Sage model to predict SSI, (Fig 10). With a probability of 0.12 which corresponds to a threshold of 7.38% of Spine Sage, we could identify 5/7 of true positives (sensitivity = 71.43%) and 35/43 of true negatives (specificity = 81.40%), which makes a total of 40/50 correctly classified patients (80% of correctly classified). High value of the spine Sage score increases the likelihood of developing a SSI (Fig 10).

Table 1 : summary of the variables between the 2 groups and results of univariate logistic regression.

| Variables | Groupe without Infection N(%) | Groupe with Infection N(%) | OR | P-value |
|---|---|---|---|---|
| N | 43(86) | 7(14) | - | - |
| Age, mean(sd) | 60.33(sd 14.50) | 59.57 (sd 12.37) | 0.99 | 0.89 |
| Sex(Male) | 11(25.58%) | 5(71.53%) | 7.27 | 0.03 |
| Sex (femme) | 32 (74.42) | 2 (28.57) | - | - |
| Cerebrovascular Disease | 2(4.65%) | 0(0) | - | - |
| Chronic Obstructive Pulmonary Disease | 3(6.98%) | 1(14.29%) | 2.22 | 0.51 |
| asthma | 5 (11.63) | 0 (0) | - | - |
| Hypertension | 14 (32.55) | 3 (42.85) | 1.55 | 0.59 |
| Rheumatoid Arthritis | 1 (2.32%) | 0 | - | - |
| Renal disease | 3 (6.81) | 1 (14.28) | 2.22 | 0.51 |
| pre-existing Neoplasm | 9 (20.93) | 0 | - | - |
| history of Syncope or Seizure | 1 (2.32) | 0 | - | - |
| anémia | 0 | 0 | - | - |
| bleeding disorder | 0 | 0 | - | - |
| Diabetes | 3 (6.98%) | 2 (28.57%) | 5.33 | 0.10 |
| Congestive heart failure | 2(4.65%) | 0(0%) | - | - |
| revision surgery | 11(25.58%) | 5(71.43%) | 7.27 | 0.03 |
| previous spinal surgery | 12(27.91%) | 4(57.14) | 3.44 | 0.14 |
| Antécédent de complication cardiaque | 3 (6.98) | 0 (0.0) | - | - |
| number of previous spine surgery | 0.53 (0.96) | 1.00 (1.00) | 1.55 | 0.25 |
| previous cardiac complications | 3 (6.98%) | 0 | - | - |
| BMI | 26.57 | 28.83 | 1.18 | 0.76 |

| | | | | |
|---|---|---|---|---|
| ASA score | 1.95 (0.53) | 2 (0.58) | 1.18 | 0.83 |
| Surgical invasiveness index | 9.86 (1.81) | 13.43 (4.96) | 1.45 | 0.013 |
| Pourcentage spine sage | 6.79 (2.68) | 9.25 (3.33) | 1.25 | 0.052 |
| Diagnostic 1 : spondylolisthésis | 40 (93.2) | 2 (28.57) | 0.03 | 0.001 |
| Diagnostic 2 : lumbar spine stenosis | 20 (46.51) | 4 (57.14) | 1.53 | 0.60 |
| Diagnostic 3: discopathy | 9 (20.93) | 3 (42.86) | 2.83 | 0.22 |
| Diagnostic 4 : foraminal sténosis | 7 (16.28) | 2 (28.57) | 2.05 | 0.44 |
| Diagnostic 5 : synovial cyst | 0 (00) | 2 (28.579 | - | - |
| TLIF | 17 (39.53%) | 4 (57.14%) | 2.04 | 0.39 |
| PLIF | 26 (60.47%) | 3 (42.86%) | - | - |
| number of fixed level,mean(sd) | 1.16 (0.37) | 2.14 (1.35) | 5.28 | 0.017 |
| number of instrumented level,mean(sd) | 1.12 (0.32) | 1.57 (0.79) | 5.61 | 0.03 |
| Duration of postoperative hospital stay | 8.95 (4.34) | 29.86 (9.14) | 1.36 | 0.003 |
| Smoking | 8 (22.86%) | 3 (60%) | 7.87 | 0.09 |
| maximal follow up | 9.23 (8.96) | 15.29 (11.47) | 1.05 | 0.13 |

Table 2 : Characteristics of patients in SSI group.

| infection | date of diagnosis of infection after surgery | Type of infection | number of surgical debridement | Type de germe | Type of antibiotics | Duration of antibiotic |
|---|---|---|---|---|---|---|
| 1 | 7 days | Superficial SSI | 1 | Enterococus Faecalis + Staphylocoque epidermidis | Vancomycine + Lisezolide | 35 days |
| 2 | 4 days | deep SSI | 2 | Enterobacter cloacae complex + Pseudomonas aeruginosa | Bactrim | 10 days |
| 3 | 1 day | Deep SSI | 2 | Staphylocoque aureus (MSSA) | Levofloxacine + Rifampicine | 90 days |
| 4 | 3 days | Superficial SSI | 1 | E. coli | Levofloxacine + Rifampicine | 28 days |
| 5 | 30 days | Deep SSI | 1 | Propionibacterium acnes | Augmentin + Vibramycine | 21 days |
| 6 | 150 days | Superficial SSI | 2 | Staphylococus capitis multisensible | no | - |
| 7 | 3 days | Deep SSI | 1 | E. coli + Bacteroides fragilis + Enterobacter cloacae | Ciprofloxacine + Métronidazole | 90 days |

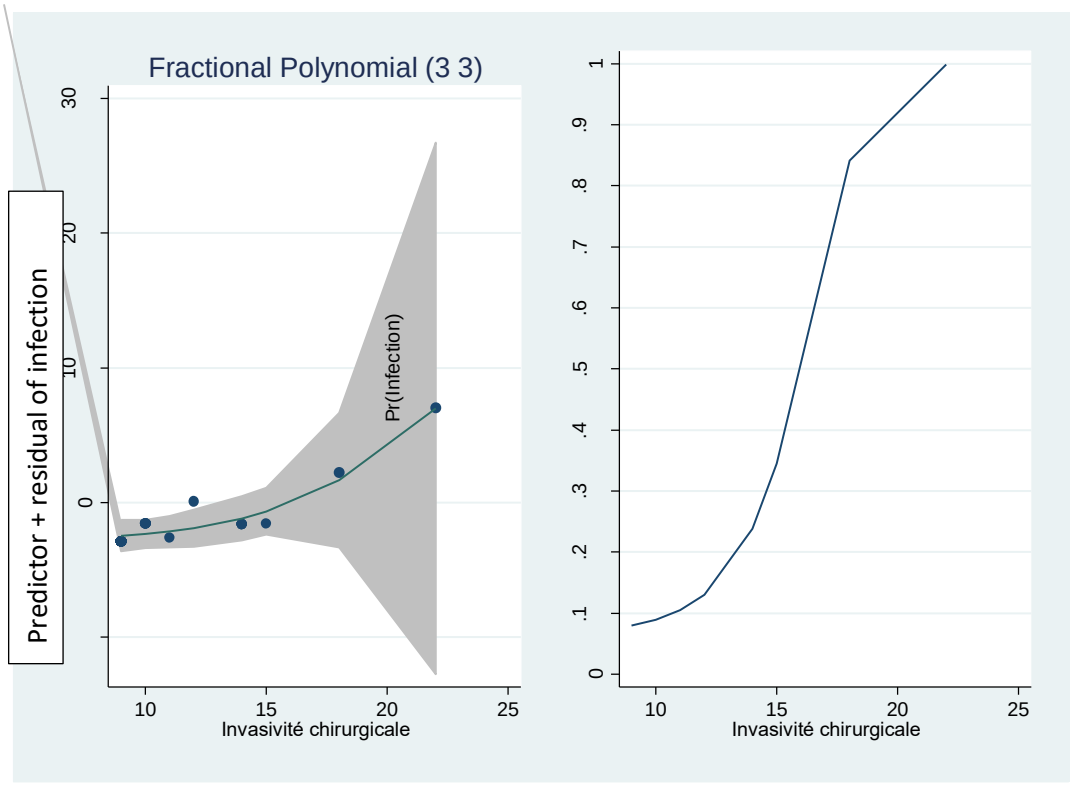



Fig 4 : Increased of risk of SSI with increased of surgical invasiveness index

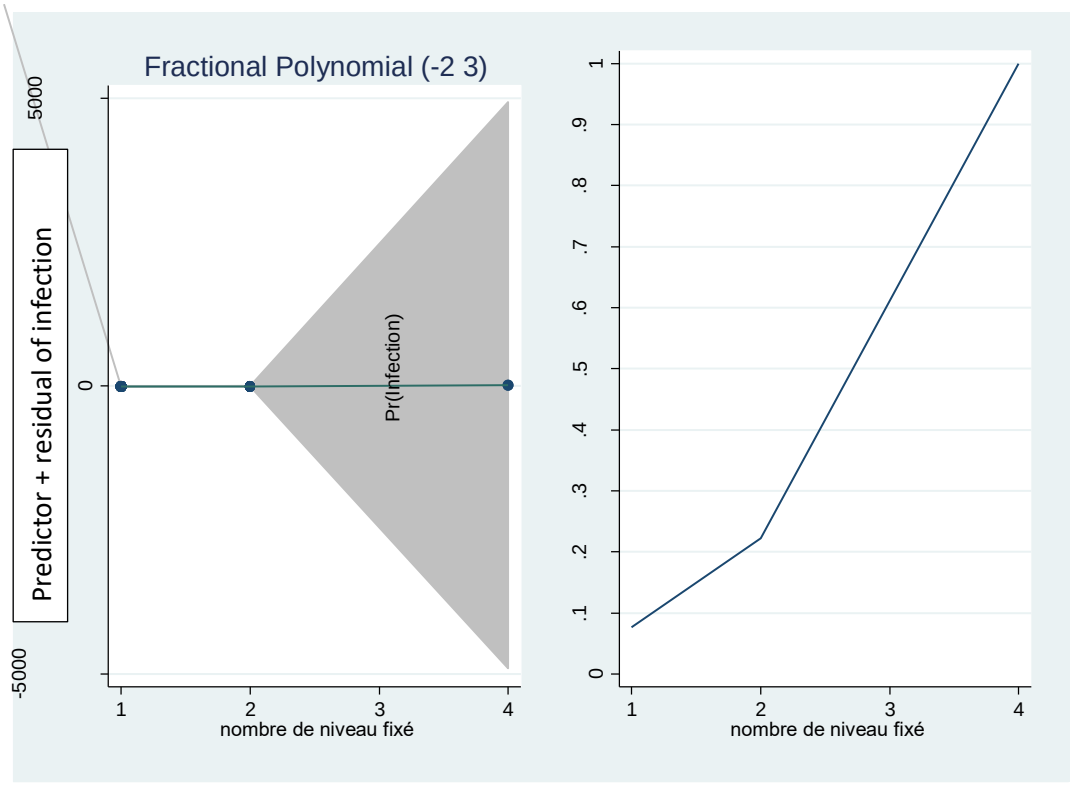


Fig 5 : increased  number of fixed level increases risk of SSI

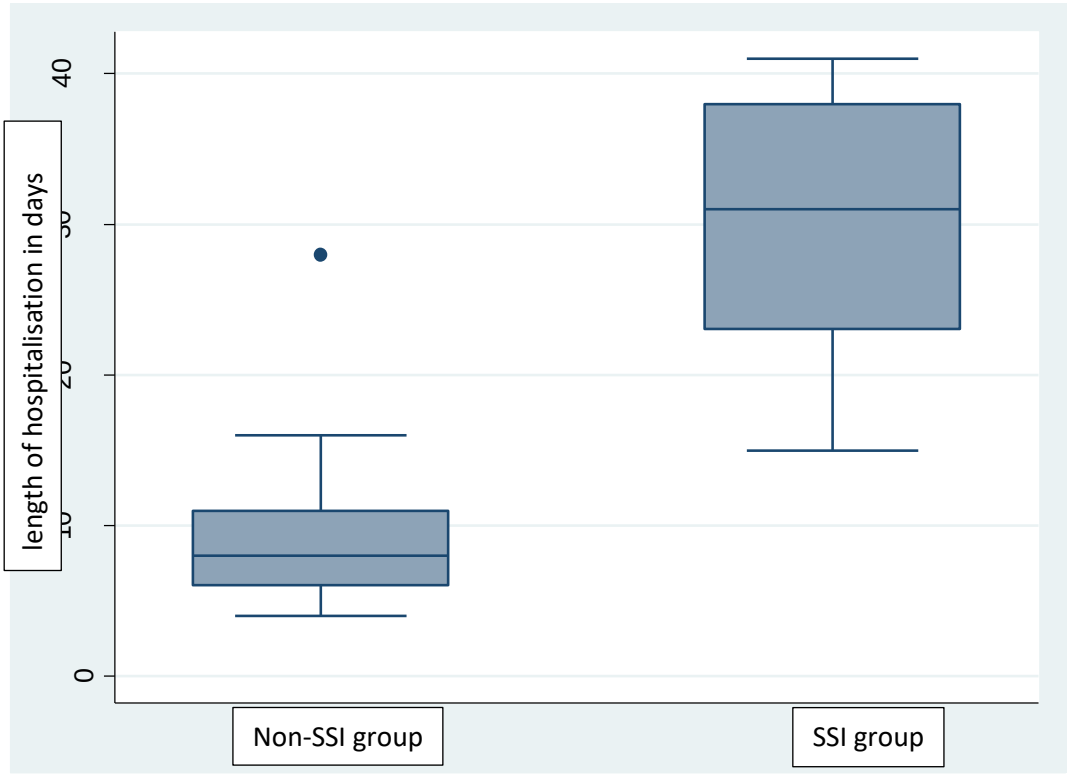



Fig 6 : we observe an increase in postoperative hospital stay, with a median of about 9 days in the non-SSI group versus about 31 days in the SSI group (average of 8.95 days (± 4.34) in non-ISO against 29, 86 days (± 9.14) in the SSI group).

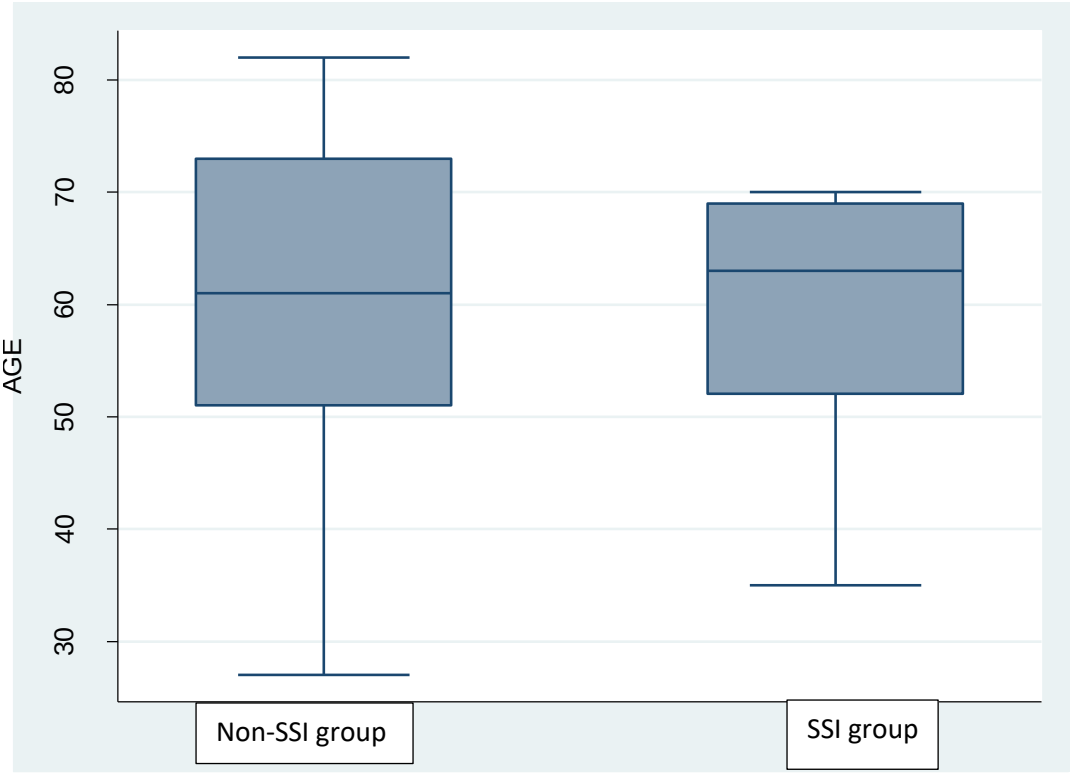



Fig 7 : Graph Box of the age for SSI group vs non-SSI group : age was not significantly associated with infection risk.

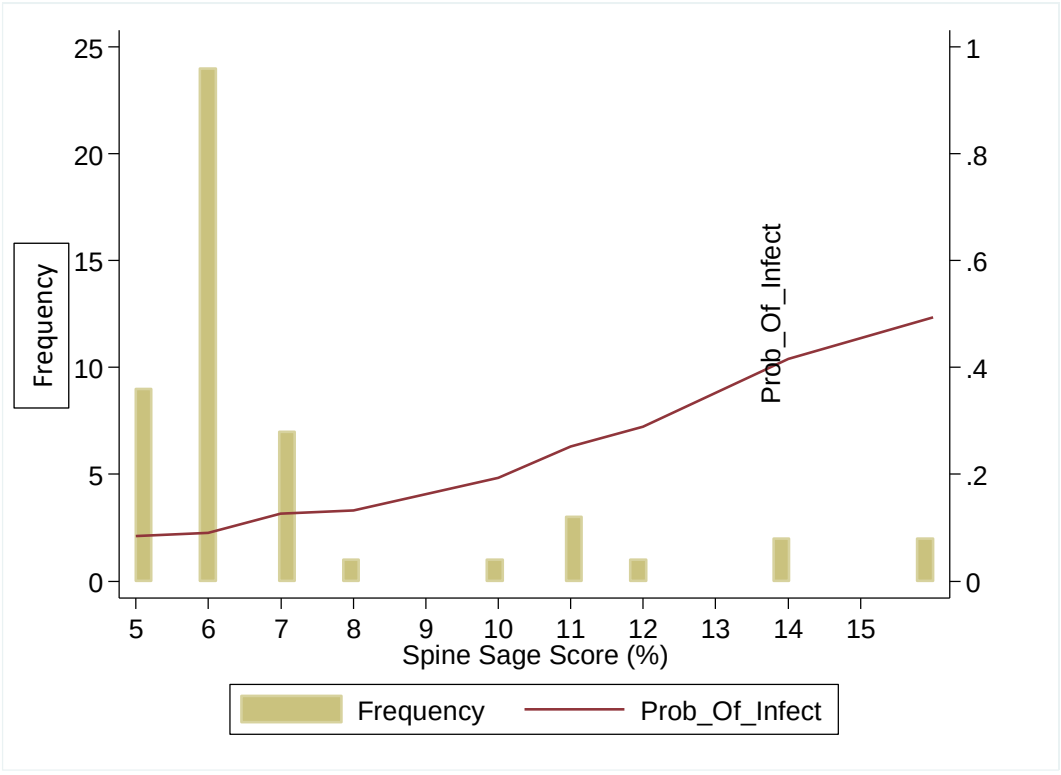



Fig 8 : The Probability of infection increases with the spine sage score

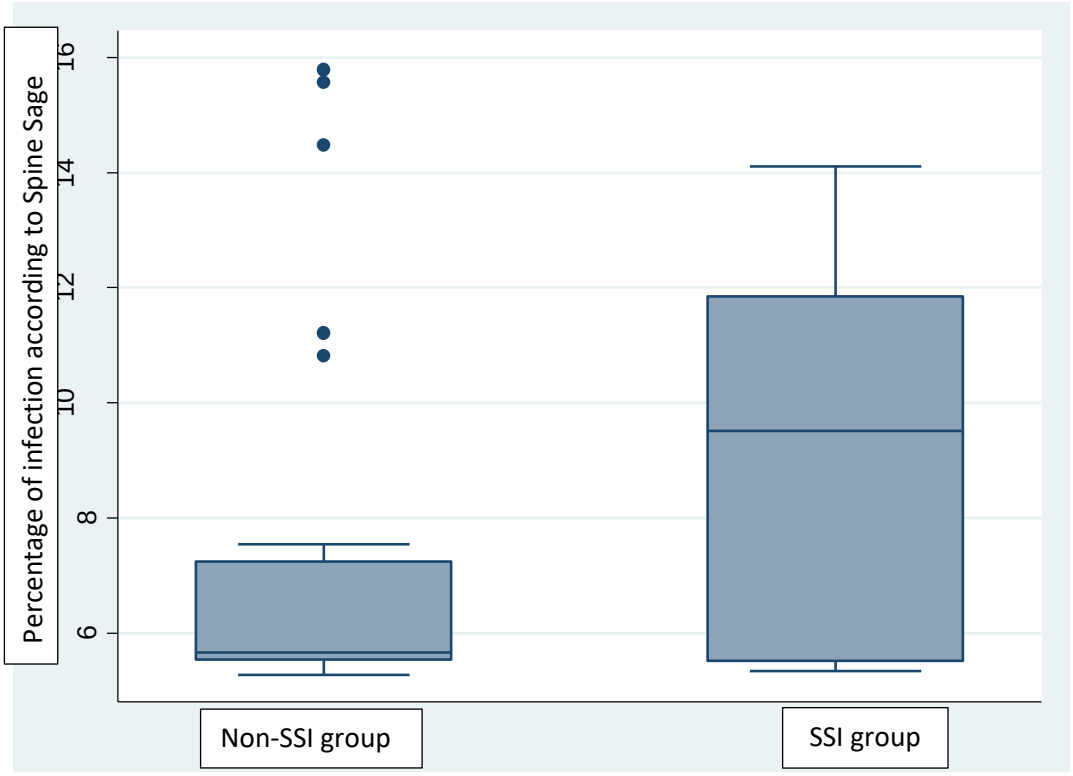
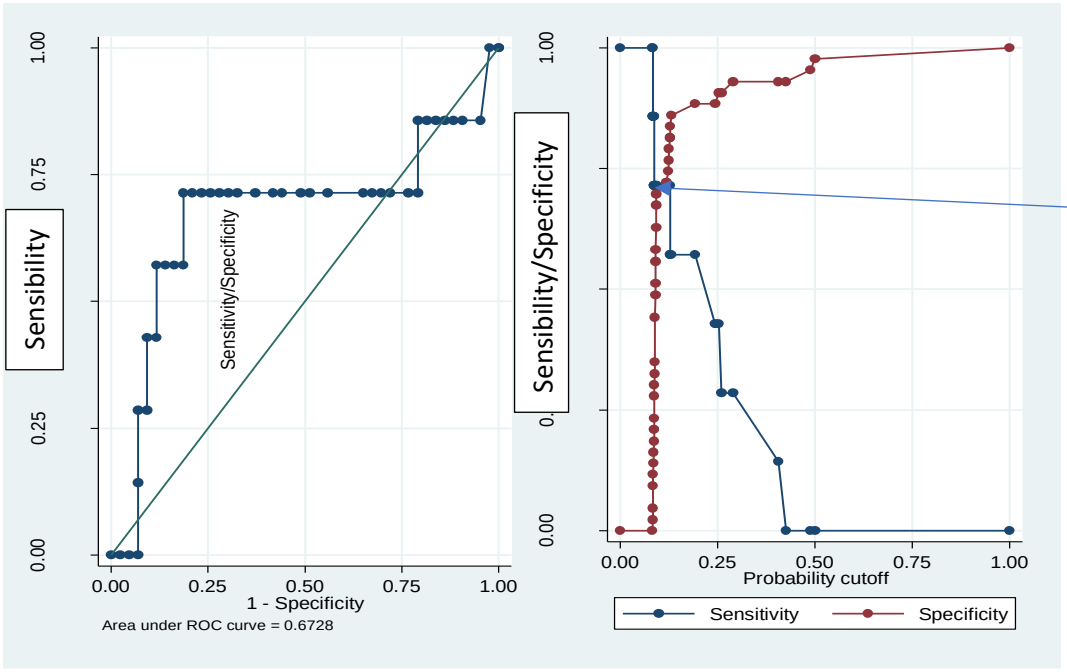



Fig 9 : Graph Box of the percentage of spine sage infection score for the SSI group vs non-SSI group, there is an area of overlapping graph box where we can not discriminate patients with SSI from patients without SSI.




With a probability of 0.12 which corresponds to a threshold of 7.38% of Spine Sage, we arrive at a sensitivity of 71.43%, a specificity 81.40% and 80% of correctly classified.

Fig 10 : The discriminatory power of the wise spine model is 67.28%

## III- DISCUSSION

A clinical prediction tool capable of estimating in percentage the risk of SSI requiring return to the operating room for debridement after a spinal surgery is of great value in guiding the decision-making of the patient and the surgeon preoperatively and allows taking steps to improve the safety of surgery.

The aim of our study was to identify risk factors associated with the SSI group and to evaluate the predictive power of the "Spine Sage" model to predict the risk of surgical site infection requiring surgical debridement after posterior lumbar fusion performed at HUG between 2011 and 2014. For this, we compared the data of two groups of patients: patients with surgical site infection requiring surgical debridement (SSI group); and patients without surgical site infection (non-SSI group). We used the Spine Sage model via the spinesage.com website which calculates the risk percentage of SSI requiring surgical debridement.
In our definition of surgical site infection, we included only patients who returned to the operating room for surgical debridement. We did not distinguish between superficial infections and deep infections in this analysis because of the small sample size and this distinction is important for future studies.

In literature, the risk of infection after instrumented fusion is of 6% or more (18). In our study, we had an incidence of 14%, which is higher than the infection rate found in the literature and is probably related with our small sample.

Staphylococcus aureus was the most commonly cultured organism in the majority of infections in the Massie JB and Heller JG study (18), whereas in our study, Staphylococcus aureus was found in only 1 in 7 patients, and in 3 out of 7 SSI patients were caused by several germs (2 or 3).

The results concerning the male sex (P = 0.03), smoking (P = 0.09), multiple level fixation (P = 0.017), increase in surgical invasiveness index (P = 0.013), SSI increases the duration of hospitalization (P = 0.003), are similar to those reported in literature, where these risk factors are statistically significantly increasing the risk of SSI (19,22,25).

Age> 60 years, diabetes, increased body mass index, previous surgical infection were statistically significant preoperative risk factors in the Fang A and Hu SS study (19) and in Meng F and Cao J study (20), while in our study, these risk factors did not statistically increase the risk of SSI: age (P = 0.89), diabetes (P = 0.10), BMI (P = 0.76), previous surgical infection (P = 0.5).

The most important medical risk factor for an adverse event in the univariate analysis of the Lee MJ and Cizik AM study was for those with a history of congestive heart failure (CHF), the chances of an adverse event in this group were 3, 68 times higher than odds for those without CHF (P <0.0001) (25) but in our study any of the infected patient had congestive heart failure.

In our study, the gain of one point of Spine Sage increases the risk of infection by 25%, and this increase is almost significant p value = 0.052.

in our study, the discriminatory power of the spine sage model including all data (N = 50 patients) measured using the ROC curve area was 0.67 which is considered poor for predicting the risk of SSI and almost comparable to that of Lee MJ and Cizik AM study (N = 1532 patients) (15) who showed an area

on the ROC curve of 0.72. This slight difference may be related to our too small sample and the fact that we limited ourselves only to degenerative diseases of the spine and to the posterior fusion.

Our study is marked by a number of limitations :

a- the small size of our sample due to the fact that we chose the patients with degenerative spine diseases and operated for posterior fusion.

b- Limitation in terms of interpretation of the results because as the sample is very small it is necessary to take the resutats with precautions.

c- On our sample we can conclude that the spine sage model is not a good predictor of SSI that requiring a return to the operating room for debridement.

## IV- CONCLUSION

SSI is a common complication of lumbar spine surgery, taking into account certain preoperative risk factors, we may suspect patients who are at higher risk of SSI and take perioperative measures. There are currently very few models that predict the risk of SSI requiring a return to the operating room for debridement and the Spine Sage model that we evaluated in our study is not very prone to predicting it and this probably because the small size of our sample and its homogeneity in terms of pathologies. For this reason, we believe that larger scale studies are needed to have more conclusive results.

Based on my study the Spine Sage model is not a good predictor of SSI requiring a return to the operating room for a debridement, which is contrary to the conclusion of the Washington study. To be able to recommend or not the Spine Sage model in daily practice, it would be necessary to make studies on a larger sample and on more pathology (degenerative, traumatic, tumoral) to have more solid results.

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