UNIVERSITE DE NANTES

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FACULTE DE MEDECINE

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Année : 2019 N° 2019-200

THESE

pour le

DIPLOME D'ETAT DE DOCTEUR EN MEDECINE

par

Boris POSTAIRE

né le 04/12/1990 à Caen

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Présentée et soutenue publiquement le 17/10/2019

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ANALYSE MEDICO-ECONOMIQUE DE L'ETUDE BATTLE : résultats préliminaires
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BATTLE TRIAL, A COST EFFECTIVENESS AND UTILITY ANALYSIS,
Preliminary results

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Président et Directeur de thèse : Monsieur le Professeur Yann GOUEFFIC

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Remerciements :

A Monsieur le Pr Yann GOUEFFIC :

Pour avoir accepté de diriger cette rédaction et de présider mon jury de soutenance. Je te remercie de m'avoir accepté dans cette équipe de chirurgie vasculaire Nantaise et de m'avoir appris à tenter en chirurgie. Tous mes vœux de réussites.

A Monsieur le Pr PICQUET :

Pour avoir accepté et me faire l'honneur de faire partie de mon jury. Je vous remercie pour vos qualités d'enseignement vues à maintes reprises au collège et votre disponibilité. Je vous exprime mon admiration sincère.

A Monsieur le Dr KALADJI :

Pour avoir accepté et me faire l'honneur de faire partie de mon jury. Merci pour cet excellent semestre à Rennes, tu es toujours excellent, disponible, pédagogue, (et un parfait DJ pour anastomoses). Tu es un modèle avec un grand C.

A Monsieur REPARATE RETALI :

Pour avoir accepté de faire partie de mon jury. Merci de m'avoir supporté et aidé à réaliser cette thèse, et de m'avoir fait découvrir un sujet plus que complexe. Merci pour ta disponibilité.

Au Dr CHAILLOU :

Merci pour absolument tout. Votre talent, votre pédagogie, votre patience, votre respect, tout. Vous êtes le maître pour tous les internes passés à Nantes, et je ne déroge pas à la règle. Et tant que les artères seront grignotées j'espère faire perdurer votre style tout au long de ma vie chirurgicale.

Au Dr COSTARGENT :

Je te dis merci, pour avoir été toujours au côtés des internes et m'avoir rapidement fait confiance. Je ne te souhaite que du bon pour le futur, et on continuera, entre guillemets, à parler comme toi, sois en sûr.

Au Dr MAUREL-DESANLIS :

Je te remercie pour m'apporter de la rigueur et du soutien dans les travaux scientifiques, j'ai hâte de travailler avec toi ces prochaines années.

Aux Rennais :

A M. CARDON, que je n'ai pas assez croisé mais qui a su réunir cette équipe parfaite, A. M. LUCAS pour avoir pu rencontrer l'original de M. COSTARGENT, A ELODIE cette patte chirurgicale impressionnante et la meilleure chanteuse du bloc (ou deuxième meilleure ?), A REMY et ALEXANDRE, vous avez été ceux qui m'ont fait grandir en me faisant une grande confiance, et ça aura toujours une importance fondamentale pour moi, merci !

Aux Nantais :

À MARIE, la meilleure chanteuse du bloc (ou deuxième ?) merci pour m'avoir soutenu depuis mon petit 4eme semestre jusqu'à maintenant. Et A CHARLOTTE profite de l'air D'Aquitaine.
A FLORA et à NICOLAS, je regrette de ne t'avoir pas connu un peu plus tard mais j'ai beaucoup apprécié cet année à être ton interne.

Aux Poitevins et A ROMAIN qui m'a toujours respecté et fait confiance,

Aux Yonnais, Merci à PAV, merci aux Dr POIRIER, MARRET et LE PAUL, qui m'ont dégagé le temps nécessaire à la réalisation de ce travail.
Même si je ne peux pas tous vous citer, je remercie aussi toute l'équipe chirurgicale de la Roche sur Yon, chez qui l'année et demi passée a toujours été un plaisir, en orthopédie comme en viscéral, ainsi que l'ensemble de l'équipe de CTCV, chez qui cette première année de chirurgie restera gravée dans ma vie.

A mes Co-internes :

Beaucoup trop de remerciements s'imposent…
A Guillaume l'inimitable marcheur sur la tête, à Basile l'imperturbable bel homme et Alexandra fidèle et inimitable. Notre première année restera la plus importante.

A Tom potter qui ira loin, A Monique Le Kinanic et Doudou, on pense à toi dans le froid du nord ; à Rémy déjà cité,

A Blandine, benoit et le Ventoux, Jean Martin, courage mon pauvre et Vilfrite Bertho,

A tous les internes de Poitiers croisés en CTCV, je regrette de ne pas vous avoir revus depuis,

Aux co-internes de mon 3ème semestre à la Roche,

Aux internes d'anesthésie, quel que soit leurs grades et leurs armes, je maintiens le secret mais suis sûr que vous vous reconnaitrez !

A d'autres Co internes et amis, Lili, Lucas, Benjamin, Ismaël, Mélodie, Paul, Astrid, Morgan, Yonis, Marie, Arthur et d'autres…

A mes vieux amis ne m'ayant pas connu médecins,

A ma famille,

A Hélène, énormément,

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Liste des abréviations:

*ATIH : Agence Technique Information sur l'Hospitalisation

*BMS : Bare Metal Stent

*CCAM : Classification Commune des Actes Médicaux

*CNAM : Caisse Nationale d'Assurance Maladie

*DCB : Drug Coated Balloon

*DES : Drug Eluting Stent

*DIM : Département d'Information Médicale

*DMI : Dispositif médical implanté

*E: Euros

*EQ5D : EuroQol 5 Dimension

*GHS : Groupement Homogène de Séjour

*HAS : Haute autorité de santé

*ICER : Incremental Cost Effectiveness Ratio

*NHS: National Health Insurance

*PAOD: Peripheral artery obliterating disease

*PMSI : Programme Médicalisation Système Information

*POBA : Plain Old Balloon Angioplasty

*SFA: Femoral Superficial Artery

*TASC: Trans Atlantic Society Consensus

*TLR: Target Lesion Revascularization

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I. ABSTRACT:

a. Background

Recent trials tend to show better patency with Drug Eluting Stent (DES) versus Bare Metal Stent (BMS) in femoropopliteal artery, but with no idea of its cost effectiveness. The BATTLE study compares these two techniques.

b. Objectives

We evaluate the cost effectiveness and cost utility of DES Zilver ® PTX versus BMS Misago ® in the treatment of symptomatic intermediate femoropopliteal lesion thanks to the BATTLE trial.

c. Method

BATTLE is a controlled, randomized, multicenter, trial comparing stenting in symptomatic patients with de novo lesions of the superficial femoral artery or proximal popliteal artery, including 186 patients between 25 March 2014 and 31 August 2016 , collecting clinical data and an EQ5D-3L questionnaire at 1, 12 and 24 months.

We performed an economic analysis alongside this trial collecting costs with the French health care system and ATIH data center, with a case-mix method. We first provided a base case study, Then we did a sensitivity analysis to perform a multiple imputation.

We calculated the quality-adjusted life-years (QALYs) for each patient and then provided a cost utility study based on the ICER.

d. Results

1.36 [ic 1.24-1.47] Zilver PTX® stent and 1.2 [ic1.11-1.28] Misago® were implanted per procedure resulting in a significant difference (p = 0.0271). Total cost for Misago® stenting group per patient was 5425.58E versus 7116.8E for Zilver PTX® one's; Initial cost was 2407.37E versus 2985.30E; device cost 1245.97E versus 1393.23E; follow up during the first year, 244.30E versus 226.79E and during the second year 37.14E versus 37.12E; and rehospitalization during the first year 826.82E versus 2193.82E, and during the second year 387.76E versus 650.14E. Target Limb related cost was 1 691.22 higher in Zilver PTX® group. All patients showed a better quality of life after procedure but QALYs are greater in the Misago® group and QALYs at M1. M12 and M24 were respectively of 0.54; 0.83, 0.75 and 0.86 in the Misago® group, and 0.56, 0.78, 0.74 and 0.74 in the Zilver PTX® group. ICER calculated for Zilver PTX® is -21000E per QALYs.

e. Conclusions

In BATTLE Trial, Zilver PTX® showed a higher procedural cost, a higher overall cost and a lower quality of life. Zilver PTX® stent failed to show better cost utility in treatment of femoropopliteal artery lesion at two years.

II. INTRODUCTION:

The Peripheral artery obliterating disease (PAOD) is defined by a narrowing of the size of the lower limbs arteries, which results in a drop in the systolic pressure index. When symptomatic, the PAOD comes in two forms: stress ischemia, responsible for claudication and critical ischemia, responsible for rest pain and, or trophic disorders. There is an important risk for the lower limb to progress toward critical ischemia from 21% to 5 years, of which 4 to 27% will suffer from an amputation (1) (2).

PAOD affects more than 200 million patients worldwide and 11% of French people over 40 years old (3). In 2015, 575200 patients were treated for PAOD (1 women for 2 men), mean age 72 years, representing 1.811 M euros, with 799 M for in hospital cost and 2.630 Euros per person during a year. (4)

Endovascular first line treatment became the gold standard for femoropopliteal revascularization showing less complications and better results; and not only for short lesions as initially recommended in the TASC II (5).

These therapeutics have shown very good results regarding patency and limb viability but with larger number of reinterventions due to high rates of restenosis.

With numerous clinical trials in favor of self-expanding bare metal stents (BMS) over percutaneous angioplasty (PTA), procedures have changed, but in-stent restenosis rates are still high.

Drug eluting devices, represented by drug eluting balloon and stents, deliver small doses of anti-mitotic drug in arterial wall to inhibit the process of myointimal hyperplasia and therefore, decrease restenosis rate.

Some studies have shown superiority of drug eluting technologies over standard care repreensented by BMS (6), (7), (8).

The 5-Year results of the Zilver PTX® Randomized Trial (8) showed that DES with Zilver PTX® was significantly superior to the standard care group (79.8 % versus 59.3 %) in clinical benefits. Evaluation of the provisional stent groups also showed a significantly higher 5-year clinical benefit for provisional DES than for provisional BMS (81.8 % versus 63.8 %).

In comparison of patients treated with standard care, DES treated patients had a 40 % risk reduction for reintervention at 5 years.

However drug eluting devices require more technology for its development and comes with higher cost.

Recently, the Cost-Effectiveness Results From the IN.PACT SFA II (9) Trial showed, in randomized controlled study including 331 patients, that despite a superior cost for DCB (drug coated balloon) during the first intervention, its better efficacy results in a better efficiency. However this study compare DCB with PTA which is no longer recommended in the femoropopliteal revascularization. (10)

Erwin de cock and al (11) estimated the cost effectiveness using Zilver PTX® stent against BMS. The model estimated a cumulative 5-year budget reduction of 6,807,202E for a projected population of 82,316 patients, with 21,361 treated with the Zilver PTX®. Moreover, in the Erwin de cock study (11), the theoretical model predicted a cost of 5.152E with a Zilver PTX® treatment and 5.503E for BMS treatment at 5 years.

In September 2011, France decided to reimburse Zilver PTX® at 1000E, which was 19% higher cost than BMS (12). Nowadays, a nitinol BMS stent costs 750E per stent and Zilver PTX® cost 830E per stent. Because of this increasing cost, it is important to know the real cost effectiveness of DES in PAOD treatment.

The BATTLE trial is the first study that compared bare metal stenting to paclitaxel-eluting stenting. This prospective, randomized, controlled, multicentric study compared the drug eluting Zilver PTX® stent versus the Misago® RX bare metal stent in the treatment of intermediate length femoropopliteal lesions in patients with symptomatic peripheral arterial disease. We assessed the cost utility analysis of the BATTLE trial.

III. METHOD:

We conducted an economic analysis from BATTLE trial, a prospective, randomized, controlled, multicentric and national study comparing DES Zilver PTX® to BMS Misago® in 186 patients from the 25th of March 2014 to the 31th of August 2016. They had intermediate femoro popliteal lesion with a Rutherford score from 2 to 5. The BATTLE trial evaluated the freedom from in-stent restenosis at 1 and 2 years. Patients had to fulfill the EQ5D-3L quality of life questionnaire at inclusion and at M1, M12, M24.

- Hospitalization costs.

  These costs were assessed using a Case Mix method.

  We used the French healthcare system, collecting data thanks to the locals DIM of each center to collect PMSI by the ATIH data center.

  At first, we collected the CCAM codes acts, a French nomenclature to code the gestures practiced by surgeons and the cost of the DMI (Zilver PTX® or Misago®).

  Then, we assessed the costs of the hospital diagnosis, the principal diagnosis and the connected diagnoses which are the French items of the hospitalization cost on which the reimbursement politics of the French healthcare system are based.

  The cost of the hospitalization length stay was based on the GHS.

Regarding the DMI, the cost effectiveness study is based on the reimbursement rates from the French healthcare system in agreement with the CNAM website. These rates changed during the two years of the inclusion period.

LPP rate of Zilver PTX® was 1000E in 2014, 875E in 2015 and 840E in 2017.For Misago®, LPP rate was 841,52E at the beginning and 800E at the end.

For this study, all costs have been updated on the basis of the 2019 costs, That is to say 830E for Zilver PTX® and 750E for Misago®.

With those data, we were able to target only the relative cost for of each patient to the health insurance system in term of first hospitalizations and all subsequent hospitalizations linked to the vascular care. Indeed, with the CRF and the PMSI data, we can precisely say if the subsequent hospitalization of a patient was linked to the first pathology treated in BATTLE trial.

- Cost effectiveness

To appreciate the effectiveness, in the BATTLE trial we collected at each follow up (M0, M1, M12, M24) the EQ5D-3L questionnaire as recommended by the HAS and OMS. We calculated the quality-adjusted life-years (QALYs) for each patient. Then we used a Mainstream Method as multiple imputation method to assess missing data.

- Statistical analysis

Randomization in the BATTLE trial showed no difference between the two groups except for diabetes mellitus.

Until now, we collected data from 8 centers, representing a total of 126 patients for which all data were available. We performed a based case analysis for those 126 patients. We performed a cost effectiveness analysis for the two years on the basis of the observed data comparing the TLR ratio between the two strategies.

Then we provided a cost utility study based on the ICER as the difference in 2-year costs, divided by the difference in 2-year QALYs with either Drug eluting stenting or bare metal stenting for patients from the BATTLE trial.

We performed a one-way sensitivity analysis in order to highlight the differences in the ICERs when modifying one of the two parameters to identify which one had the greatest impact on the ICER.

IV. RESULTS:

1. Clinical follow up

In BATTLE Trial, there were no difference between the two groups except for diabetes Mellitus ($p < 0.05$) (Table 1).

	Misago® (n=85)	Zilver®PTX® (n=86)
Age (years)	68±12	71±12
Male	62 (73)	62 (72)
Hypertension	52 (61)	59 (69)
Hyperlipidaemia	61 (73)	55 (65)
Diabetes	22 (26)	41 (48)
Smoking at baseline	28 (33)	20 (23)
Coronary artery disease	34 (40)	27 (31)
Renal insuffisiency	6 (7)	8 (9)
Obesity (BMI>25)	54 (64)	58 (67)
History of ischaemic stroke or transient ischaemic attack	9 (11)	11 (13)
Vascular surgical history	26 (31)	26 (30)
History of lower limb amputation	1 (1)	0 (0)
Statin at baseline	66 (78)	67 (78)
ACE inhibitors at baseline	32 (38)	22 (26)
Antiplatelet drug at baseline	78 (92)	80 (93)
Dual antiplatelet drug at baseline	45 (53)	41 (48)
Rutherford at D0		
2	14 (16)	16 (19)
3	56 (66)	52 (60)
4	12 (14)	12 (14)
5	3 (4)	6 (7)

Table 1: Baseline demographic and clinical characteristics of the modified intention-to-treat population (extracted from BATTLE trial)

In BATTLE trial, there was no difference in term of lesion length, which was 7 (+-3) cm in the ZilverPTX ® group and 9 (+-4) cm in the Misago® group. There was no difference in term of

stent remodeling, technical success or number of concomitant ipsilateral procedure. 117 Zilver PTX® stents and 102 Misago® stents were implanted (Table 2, 3).

Stents during procedure	Misago®	Zilver PTX®	Total
1	68	57	125
2	17	27	44
3	0	2	2
Total	102	117	219

Table 2: Number of stents implanted during first procedure

That means 1.36 [IC 1.24-1.47] Zilver PTX® stent per patient and 1.2 [IC1.11-1.28] Misago® per procedure resulting in a significant difference (p = 0.0271).

group	Misago®	Zilver PTX®	
Number of stents	1.2 [1.11-1.28]	1.36 [1.24-1.47]	P = 0.0271

Table 3: Average number of stents implanted

In term of freedom from TLR there was no difference between patients in the Zilver PTX® group and the Misago® one (Freedom from TLR 91,3% vs 91.6%; HR1.2 [0.5-2.8], p =0.69)

(Figure 1).

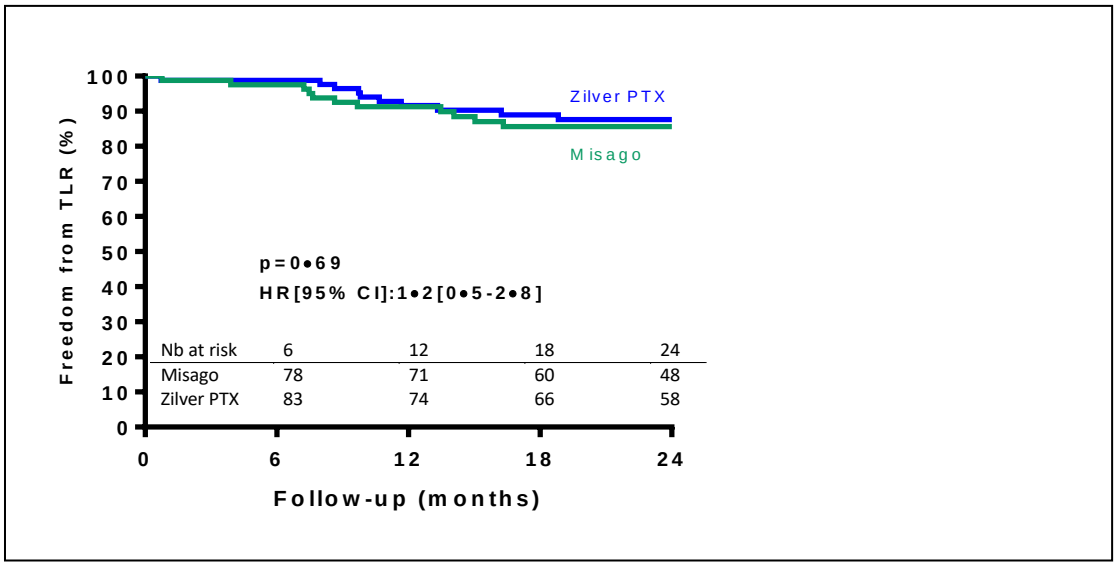

Figure 1. Freedom from target lesion revascularization (extracted from BATTLE trial)

In the Misago® group there were 53 patients who had no new hospitalization linked to the procedure, 28 had one, 3 had two and 1 had three rehospitalizations, versus respectively, 54, 20, 7 and 5 in the Zilver PTX® group. (Table 4)

Number of rehospitalization	Misago®	Zilver PTX®	Total
0	53	54	107
1	28	20	48
2	3	7	10
3	1	5	6

Table 4: Number of rehospitalization

There was an average of 0.43 [0.30-0.57] re hospitalization in the Misago® group versus 0.57 [0.38-0.76] in the Zilver PTX® one (p = 0.25) (Table 5).

Group	Misago®	Zilver PTX®	
Number of rehospitalization	0.43 [0.30-0.57]	0.57[0.38-0.76]	P = 0.25

Table 5: comparison of average rehospitalization

2. Costs:

Regarding total cost for patients who underwent the procedure with a Misago® stent was 325 704,47 E at 2 years: initial cost was 141 546,94 E, cost of the devices implanted was 80 250 E, follow up at 2 years was 13 068 E and cost of re hospitalization was 90 839 E.

Total cost for patients who underwent the procedure with a Zilver PTX® stent was 438 582,53 E : initial cost was 171 957.89 E, cost of the devices implanted was 86 380 E, follow up at 2 years 12 403 E and cost of re hospitalization was 167 840 E (table 6).

	Misago® group	Zilver PTX® group
Total cost at two years	325 704,47	438 582,53
DMI	80 250	86 380
1st Hospitalization	141 546,94	171 957.89
Follow up	13 068	12 403
Re hospitalization	90 839	167 840

Table 6: total cost of patients included in BATTLE trial (Euros)

Total cost of the first rehospitalization was, respectively in Misago® group and Zilver PTX® group, 64 055,73 E and 90 733, 39 E, 16 986,97 E and 32 754,59 E for the second one and 9796,82 E and 29 611,37 E for the third one (table 7).

	Misago® group	Zilver PTX® group
1st rehospitalization	64 055.73	90 733,39
2nd rehospitalization	16986,96	32754,59
3rd rehospitalization	9196,82	29611,37

Table 7: Total cost of rehospitalization (Euros)

Target Limb related cost was 1 691.22 higher in Zilver PTX® group. Total cost for Misago® stenting group per patient was 5425.58E versus 7116.8E for Zilver PTX® one's; Initial cost was 2407.37E versus 2985.30E; device cost 1245.97E versus 1393.23E; follow up during the first year, 244.30E versus 226.79E and during the second year 37.14E versus 37.12E; and rehospitalization during the first year 826.82E versus 2193.82E, and during the second year 387.76E versus 650.14E (Table 8).

	Misago®	Zilver PTX®
Mean total cost (n=94)	5425.58E [4511.14-6340.01]	7116.80E [5313.49-8920.11]
1st hospitalization (n=118)	2407.37E [2204.67-2610.07]	2985.30E [2495.96-3474.63]
Device cost (lpp) (n=124)	1245.97E [972.97-1518.96]	1393.23E [1157.92-1628.53]
Follow up (n=94) year 1	244.30E [176.69-311.91]	226.79E [173.94-279.64]
Rehospitalizations (n=124) year 1	826.82E [410.37-1243.27]	2193.82E [1055.13-3332.51]
Follow up year 2 (n=94)	37.14E [15.49-58.79]	37.12E [15.91-58.32]
Rehospitalizations (n=124) Year 2	387.76E [59.25-716.26]	650.14E [54.70-1245.58]

Table 8: costs per patients on based case study (Euros)

3. QALY :

For the responding patients, we calculated QALYs before the procedure (J0) and at M1, M12 and M24. They were respectively 0.54, 0.83, 0.75 and 0.86 in the Misago® group, and 0.56, 0.78, 0.74 and 0.74 in the Zilver PTX® group (Table 8). All patients showed an increased quality of life but the better score post procedure was in the Misago® group (Table 8)

QALY	Misago®	Zilver PTX®
J0 (n=148)	0.54 [0.48-0.59]	0.56 [0.50-0.63]
M1 (n=128)	0.83 [0.77-0.88]	0.78 [0.71-0.85]
M12 (n=122)	0.75 [0.69-0.82]	0.74 [0.67-0.82]
M24 (n=120)	0.86 [0.81-0.91]	0.74 [0.67-0.81]

Table 8: Evaluation of QALY score during follow up at J0, M12, M24

4. Preliminary results

In this study we had to remove 45 patients from the 171 because of a lack of information

about the cost, on the follow up data for two centers, and on all the patients for one center. But collection of data on the QALYs were complete for all centers because extracted from the CRF and not from the PMSI. We had to compare if these data with or without the missing centers influenced the multiple imputation method.

The statistical analysis remains pertinent. We compared the multiple imputation results we had with all the 126 patients, and the one with the based case on the 83 remaining patients.

The differences between QALYs in the two groups remain the same (table 8a and 8b).

Group n =126	Misago®	Zilver PTX®	
QALY base case	0.89	0.83	n=126
QALY multiple Imp.	0.87	0.82	n=171

Table 8.a: Score QALY before exclusion of the missing follow up data center

Group n= 171	Misago®	Zilver PTX®	
QALY base case	0.95	0.88	n=83
QALY Multiple Imp	0.89	0.83	n=171

Table 8.b: QALY Score after exclusion of the missing follow up data center

5. ICER

At this point, we have better QALYs in the Misago® group and a higher cost in the ZilverPTX® group. We then calculated the Incremental Cost Effectiveness Ratio. It was 21000Euros per QALY.

V. DISCUSSION :

The clinical results of the BATTLE trial failed to show clinical superiority of the Zilver PTX® against the Misago®. The Misago® stent is cheaper with an LPP reimbursed now at 750E per stent and 830E for the Zilver PTX®. With no significative difference in term of freedom from

TLR, more rehospitalizations in the Zilver PTX® group, better QALY in the Misago® group, the Zilver PTX® Stent failed to show an effectiveness especially with his increased total cost.

These results do not confirm what is mainly accepted in literature. Indeed, initial data on drug-eluting devices, as drug coated balloon, showed that they may increase the durability of endovascular treatment of superficial femoral artery disease compared with traditional bare-metal stents (BMS). Schneider and al (13) reported in In.Pact SFA trial at three-year a superiority of DCB versus PTA. The Debate SFA trial (6) showed similar results, associating BMS with the two strategies.

The MAJESTIC trial (Müller-Hülsbeck and al (7)) demonstrated that Eluvia drug-eluting stent provided higher patency rate and lower major amputation event.

At Five years of the Zilver PTX® trial, Dake and al (8) provided results demonstrating that DES with Zilver PTX® and provisional DES after PTA was superior in term of patency to Standard endovascular care such as PTA alone, and provisional BMS after PTA.

The BATTLE trial showed that the DES, Zilver PTX® achieve comparable outcomes to previous studies for intermediate lesions (6.9±3.5 cm) in term of technical success and primary patency. But the study showed no superiority of DES group in term of patency or quality of life versus BMS stent.

The first cost effectiveness studies comparing drug eluting therapy with standard care came from cardiology. Cheng and al (14) evaluated the cost-effectiveness of using DES compared to BMS for coronary heart disease. He proved that DES was more cost-effective than BMS in coronary heart disease at five years.

Baschet and al (15) performed the same kind of study in France with 117 762 patients. He showed that for a threshold of 7000E, DES had a >95% probability of being cost-effective versus BMS in term of major cardiac events. Those different studies had led to new recommendations in coronary disease...

In femoropopliteal disease, few studies showed economics analysis of drug coated devices versus standard endovascular therapy.

Diehm and al (16) explored the cost-effectiveness in femoropopliteal lesions, of DCB versus PTA in Switzerland. His model showed better cost effectiveness of DCB at 1 year (179,238Sfr vs. 333,678Sfr).

Piestzsch and al (17) used a model to study the economic impact of different endovascular treatment for GERMAN and US health system. They included thirteen studies and showed at 2 years the cost effectiveness superiority of drug eluting devices.

Sridharan and al (18) did a meta-analysis study to compare the cost-effectiveness of drug eluting devices, BMS and PTA. Despite a higher primary patency rate in DES, his study showed that the use of DCB was more cost effective than DES when using less than 2 DCB per procedure. The non-drug coated therapy was non relevant in comparison. Sridharan and al (19) also made a predictive model at 5 year using from the literature that confirm his first study.

In The U.K, Katsanos and al (20) estimated the impact of DES versus standard care in femoral treatment. In his model, devices was estimated to add 0.011 QALYs for DCB, 0.010 QALYs for DES and 0.005 QALYs for BMS, resulting in estimated ICERs of £3983, £4534 and £20 719 per QALY gained.

De Cock and al (11) assessed a study to measure the impact on the French public health care budget of introducing reimbursement for the Zilver PTX® stent using a theoretical model at 5-year horizon with French reimbursement tarifs. His model estimated a 5-year budget reduction of 6,807,202 euros for a projected population of 82,316 patients. The adoption of Zilver PTX®, despite higher procedure costs, could have led to important savings for the French healthcare system.

Recently Salisbury and al (9) provided the only based case cost effectiveness femoro popliteal study in order to evaluate the cost-effectiveness of DCB versus PTA in the IN.PACT SFA II

Trial. They showed that costs for health insurance system at two years were lower for DCB device although it is more expensive. With these data and the collection of EQ5D-3L questionnaire, they showed that there was 70 % of probability that DCB was cost-effective compared with PTA using a threshold of $50,000 per QALY gained and 79 % at a threshold of $150,000 per QALY gained. In this study they assessed same QALYs in the two groups, and lower cost in the DCB group, resulting in better cost effectiveness for DCBs.

However, our results are different.

First we have to keep in mind that these results are preliminary results with about 75% of the population of the complete study.

The BATTLE study showed better quality of life in the BMS group than in the DES one, probably due to more rehospitalizations. Some explanation may come from the distribution of population with more diabetics in the Zilver PTX® group.

Secondly, main bias in this study is that Zilver PTX® stent was available until 100 mm length and Misago® until 150 mm. Therefore, sometimes, 2 DES Stents were necessary where 1 BMS could have been used. This explain, although no difference in term of lesion length was reported, that 1.36 Zilver PTX® stents were implanted per procedure versus 1.2 Misago® ($p = 0.026$). Zilver PTX® is more expensive than Misago® and this difference change the initial cost.

Moreover, recently, Soga and al (21), in a study that compared Zilver PTX® stenting with Eluvia® stenting, both DES, showed at one year a late lumen loss significantly lower with Eluvia stenting. Freedom from TLR in the Eluvia® group tended to be higher. It is possible that the cost effectiveness of Eluvia® would be higher than Zilver PTX®, especially since those two stents are reimbursed at the same price in French health care system.

VI. CONCLUSION:

In BATTLE Trial, Zilver PTX® showed a higher procedural cost, a higher overall cost and a lower quality of life. Zilver PTX® stent failed to show better cost utility in treatment of femoropopliteal artery lesion at two years.

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RESUME

Recent trials tend to show better patency with DES versus BMS, but with no idea of its cost effectiveness. The BATTLE study compares these two techniques.
We evaluate the cost effectiveness and cost utility of DES Zilver ® PTX versus BMS Misago ® in the treatment of symptomatic intermediate femoropopliteal lesion thanks to the BATTLE trial.

We performed an economic analysis of this trial collecting costs with the French health care system and ATIH data center, with a case-mix method. We first provided a base case study, then we made multiple imputation method with sensitivity analysis.
We calculated the quality-adjusted life-years (QALYs) for each patient and then provided a cost utility study based on the ICER.

1.36 [ic 1.24-1.47] Zilver PTX® stent per patient and 1.2 [ic1.11-1.28] Misago® per procedure were implanted resulting in a significant difference (p = 0.0271). Total cost for Misago® stenting group per patient was 5425.58E versus 7116.8E for Zilver PTX® one's; Initial cost was 2407.37E versus 2985.30E; device cost 1245.97E versus 1393.23E; follow up during the first year, 244.30E versus 226.79E and during the second year 37.14E versus 37.12E; and rehospitalization during the first year 826.82E versus 2193.82E, and during the second year 387.76E versus 650.14E. Target Limb related cost was 1 691.22 higher in Zilver PTX® group. All patients showed a better quality of life after procedure but QALYs are greater in the Misago® group and QALYs at M1. M12 and M24 were respectively of 0.54; 0.83, 0.75 and 0.86 in the Misago® group, and 0.56, 0.78, 0.74 and 0.74 in the Zilver PTX® group. ICER calculated for Zilver PTX® is -21000E per QALYs.

In BATTLE Trial, Zilver PTX® showed a higher procedural cost, a higher overall cost and a lower quality of life. Zilver PTX® stent failed to show better cost utility in treatment of femoropopliteal artery lesion at two years.

MOTS-CLES

DRUG ELUTING STENT, BARE METAL STENT, FEMOROPOPLITEAL ARTERY, COST EFFECTIVENESS, COST UTILITY, QALYS

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RESUME

Des essais récents tendent à montrer une meilleure perméabilité avec le DES qu'avec le BMS, mais sans aucune idée de son rapport coût-efficacité. L'étude BATTLE compare ces deux techniques.
Nous évaluons la rentabilité et l'utilité économique du DES Zilver ® PTX par rapport au BMS Misago ® dans le traitement des lésions fémoropoplitées intermédiaires symptomatiques grâce à l'essai BATTLE.

Nous avons réalisé une analyse économique de cet essai en collectant les coûts avec le système de santé français et le centre de données de l'ATIH, avec une méthode case-mix. Nous avons d'abord fourni une étude en cas complets, puis nous avons élaboré une méthode d'imputation multiple avec analyse de sensibilité.
Nous avons calculé les scores de qualité de vie (QALY) pour chaque patient, puis nous avons fourni une étude coût-utilité fondée sur le RCED.

1,36[ic 1,24-1,47] stents Zilver PTX® et 1,2[ic1,11-1,28] Misago® par intervention ont été implantés, entraînant une différence significative (p = 0,0271). Le coût total de l'endoprothèse Misago® par patient était de 5425,58E contre 7116,8E pour l'endoprothèse Zilver PTX® ; le coût initial était de 2407,37E contre 2985,30E ; coût du dispositif 1245,97E contre 1393,23E ; suivi pendant la première année : 244.30E contre 226,79E et pendant la deuxième année 37,14E contre 37,12E ; et réhospitalisation pendant la première année 826,82E contre 2193,82E, et pendant la deuxième année 387,76E contre 650,14E. Le coût lié au membre cible était de 1 691,22E plus élevé dans le groupe Zilver PTX®. Tous les patients ont montré une meilleure qualité de vie après l'intervention, mais les QALYs sont plus importantes dans le groupe Misago® et les QALYs à M1. M12 et M24 étaient respectivement de 0,54 ; 0,83, 0,75 et 0,86 dans le groupe Misago®, et 0,56, 0,78, 0,74 et 0,74 dans le groupe Zilver PTX®. L' ICER calculé pour Zilver PTX® est de -21000E par QALYs.

Dans l'essai BATTLE, Zilver PTX® a montré un coût de procédure plus élevé, un coût global plus élevé et une qualité de vie inférieure. Le stent Zilver PTX® ne montre pas une meilleure efficience que le stent Misago® dans le traitement des lésions artérielles fémoro-poplitées après deux ans.

MOTS-CLES

STENT ACTIF, STENT NU, AXE FEMORO POPLITE, ANALYSE COUT UTILITE, ANALYSE COUT EFFICACITE, QALYS