

INTRATYMPANIC INJECTIONS AND MENIERE DISEASE : is there a consensus today?



Marie-José FRAYSSE MD
Otology and Otoneurology department
University Hospital - TOULOUSE



**IFOS COURSE
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24/27 Nov 2019**

INTRODUCTION



- Menière's disease (MD) is characterized by idiopathic endolymphatic hydrops (EH) and results in repeated attacks of vertigo, hearing loss, tinnitus, and aural fullness in the affected ear.
- Numerous treatments exist but aren't ideal without identifying causes
- The conservative treatment is, in some cases, insufficient
- In this context ITI became unavoidable within the therapeutic spectrum of options.

INTRODUCTION



■ To propose ITI to a patient with MD implies the following considerations:

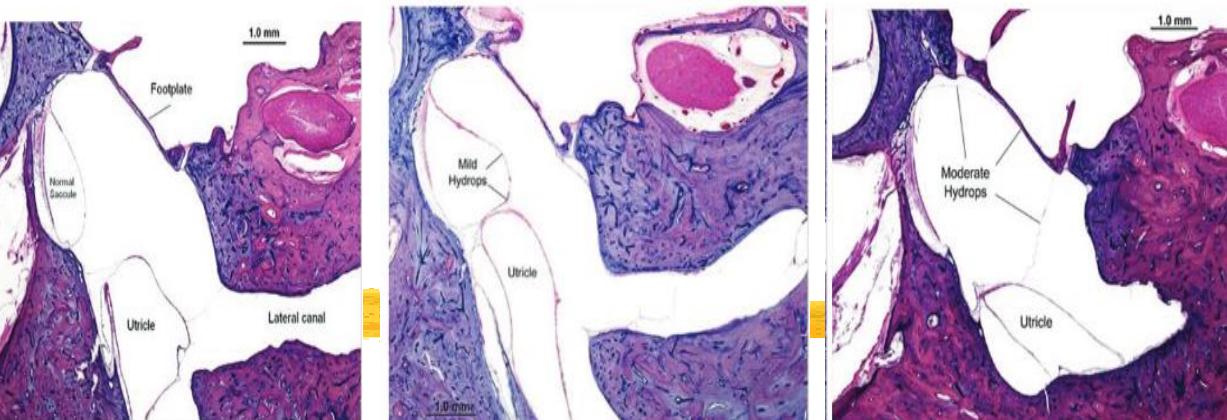
- Being confident with the diagnosis
- Having tried various types of classical treatments
- Evaluating the functional disability of the patient

Which product to inject ? Based on bibliography and experience

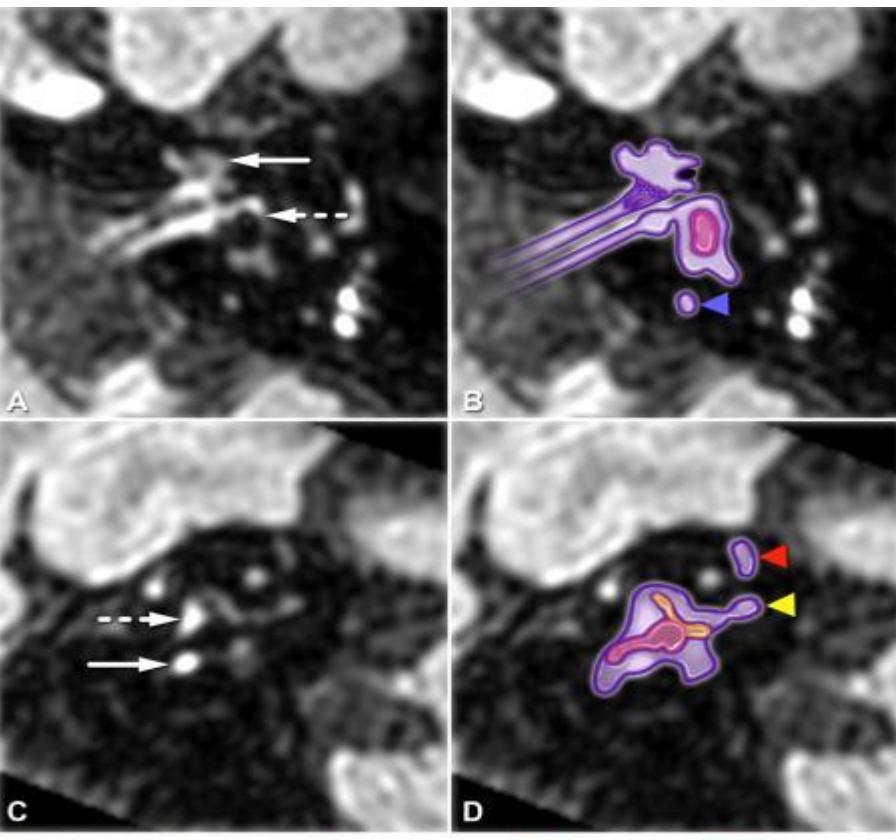
Which protocol to be used ? Explain to the patient importance of the follow-up

Not forgetting that treatments are designed for controlling symptoms and improving life quality.

Pathophysiology Ménière disease



- Based on the Hydrops endolymphatic (HE) in histology and on MRI protocol hydrops (Gado 4h acquisition)
- HE doesn't explain everything: asymptomatic forms, large variety of symptoms and remission duration.



► PSC ▲ LSC ▶ SSC ■ Utricle ■ Saccule

ITI principal and Ménière disease



- Diffusion at FR and FO windows level
- Allowing high concentration (x 260) of injected product without side effects from the systemic treatment
- Non invasive method, external, localized side effects uncommon
- Abundant literature ,Gentamicin has an indisputable effect
- Corticosteroid: which mode of action ? Few studies existing versus placebo effect
- Recent publications compare Gentamicin effects to corticosteroid's (Dexamethasone or Methylprednisolone)
- Where do we really stand ?

Which protocols in 2019 ?

Therapeutic recommendations sforl 2016



- 1st period: Medical treatment and hygiene/dietary measurements (low invasiveness)
- 2nd period: ITI of corticoids and/or Sac surgery (low invasiveness)
- 3rd period: Treatment of the vestibular function (gentamicin - high invasiveness)
- 4th period: Suppressor treatments of all vestibular functions (surgical labyrinthectomy or vestibular neurotomy - maximum invasiveness).

ITI INDICATIONS: 3 QUESTIONS



DECISION CRITERIA :

- Is it surely a Meniere disease ?
- Is the Meniere disease disabling for the patient ?
- All available solutions have been tried out ?

Diagnostic criteria AAO-HNS 2015 and Barany Society



Definite Ménière's disease:

- A. Two or more spontaneous episodes of vertigo lasting 20 minutes to 12h
- B. Audiometrically documented low to medium frequencies SNHL in the affected ear on at least one occasion before, during or after one of the episodes of vertigo
- C. Fluctuating aural symptoms (hearing, tinnitus or fullness) in the affected ear
- D. Other causes made unlikely

Diagnostic criteria AAO-HNS 2015 and Barany Society



Probable Ménière's disease:

- A. At least two episodes of vertigo or dizziness 20 min – 24 hours in duration**
- B. Fluctuating aural symptoms (hearing, tinnitus or aural fullness) in the affected ear**
- C. Other causes made unlikely.**

Lopez-Escamez JA, Carey J, Chung W-H, Goebel JA, Magnusson M, Mandalà M, Newman-Toker D, Strupp M, Suzuki M, Trabalzini F, Bisdorff A. **Diagnostic criteria for Menière's disease.** J Vestib Res. 2015;25(1):1–7.

Vestibular migraine: Diagnostic criteria

Consensus document of the Bárány Society and the International Headache Society

Thomas Lempert^{a,*}, Jes Olesen^b, Joseph Furman^c, John Waterston^d, Barry Seemungal^e, John Carey^f, Alexander Bisdorff^g, Maurizio Versino^h, Stefan Eversⁱ and David Newman-Toker^j

^aDepartment of Neurology, Schlosspark-Klinik, Berlin, Germany



Table I. Current definitions of vestibular migraine and Menière's disease.

Vestibular migraine	(a) At least five episodes with vestibular symptoms of moderate or severe intensity, lasting 5 minutes to 72 hours (b) Current or previous history of migraine with or without aura according to the International Classification of Headache Disorders (ICHD) (c) One or more migraine features with at least 50% of the vestibular episodes: - headache with at least two of the following characteristics: one-sided location, pulsating quality, moderate or severe pain intensity, aggravation by routine physical activity - photophobia and phonophobia - visual aura (d) Not better accounted for by another vestibular or ICHD diagnosis
Menière's disease	(a) Two or more spontaneous episodes of vertigo, each lasting 20 minutes to 12 hours (b) Audiometrically documented low- to medium-frequency sensorineural hearing loss in one ear, defining the affected ear on at least one occasion before, during or after one of the episodes of vertigo (c) Fluctuating aural symptoms (hearing, tinnitus, or fullness) in the affected ear (d) Not better accounted for by another vestibular diagnosis

Adapted from Lempert et al. (11) for vestibular migraine and Lopez-Escamez et al. (22) for Menière's disease.

Diagnostic criteria for Vestibular Migraine (VM)

Barany society

Journal of Vestibular Research 22 (2012) 167–172
DOI 10.3233/VES-2012-0453
IOS Press

167

Vestibular migraine

- A. At least 5 episodes with vestibular symptoms with moderate to severe intensity and lasting from 5 minutes to 72 hours
- B. Antécédents current or past migraines with or without aura according to ICHD ;
- C. One or several migraine phenomenon accompanying at least 50 % of vestibular episodes:
 - headaches with at least 2 of the following characteristics: unilateral localization, *pulsating, moderate to severe pain, aggravation due to basic physical activities,*
 - photophobia and phonophobia,
 - Visual aura;
- D. No better explanation through other vestibular or ICHD diagnosis.



Diagnosis criteria from Barany society

Journal of Vestibular Research 22 (2012) 167–172
DOI 10.3233/VES-2012-0453
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Vestibular migraine: Diagnostic criteria

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^aDepartment of Neurology, Schlosspark-Klinik, Berlin, Germany

Vestibular migraine most likely type:

- A. At least 5 episodes with vestibular symptoms with moderate to severe intensity, going from 5 minutes to 72 hours;
- B. Only one of B and C criterion for vestibular migraine is for-filled (antecedents of migraine or migraine phenomenon during the episode) ;
- C. No better explanation through another vestibular or ICHD diagnosis.

Differential diagnosis: Ménière's disease



Therefore sometimes difficult to assess based on a spectrum of arguments:

- Clinical history +++
- Related signs, triggers,
- Clinical exam,
- Deafness evolution

N. T. Shepard, "Differentiation of Meniere's disease and `migraine-associated dizziness: a review,'" *Journal of the American Academy of Audiology*, vol. 17, no. 1, pp. 69–80, 2006.

Differential diagnosis: VM and Ménière's disease



- Signs and symptoms can often be correlated
- In favor of VM:
 - Short crisis < 15 minutes or longer > 24 h
 - Photo-phonophobia, anxiety, frequent palpitations
 - High visual sensitivity
 - **Signes centraux** from clinical exam +++
 - Fluctuating deafness ON LOW FRQUEoften bilaterally but rarely permanent nor evolutive.
+++

2/ Is it actually disabling? Every options have been explored?

1/ Crisis: frequency (6 months to 1 year)

2/ Tumarkin attacks = Major criteria

3/ Handicap evaluation

- Anxiety, stress: HADS survey
- Vertigos: intensity and survey DHI, AAO-HNS
- Professional impact (sick leave)
- Driving forbidden ?

Tableau 3.5. Échelle de niveau fonctionnel en six stades.

- | |
|---|
| 1. Ma maladie vertigineuse n'a aucun retentissement sur mes activités. |
| 2. Quand j'ai un vertige, je dois arrêter mes activités pour un certain temps, mais le vertige s'arrête rapidement et je peux les reprendre. Je continue à travailler, à conduire, et m'implique dans la plupart de mes activités. Je n'ai pas eu besoin d'aménager mes projets ni de faire certaines adaptations de mes activités à cause de mes vertiges. |
| 3. Quand j'ai un vertige, je dois arrêter mes activités pour un certain temps, mais le vertige finit par s'arrêter et je peux reprendre mes activités. Je continue à travailler, à conduire, et m'implique dans la plupart de mes activités. J'ai dû aménager mes projets et adapter mes activités à cause de mes vertiges. |
| 4. Je suis capable de travailler, conduire, m'occuper de ma famille, de m'impliquer dans la plupart de mes activités, mais cela me demande constamment des efforts importants, et d'économiser mon énergie. |
| 5. Je suis incapable de travailler, de conduire, de m'occuper de ma famille, ou de m'impliquer dans la plupart des activités que j'avais l'habitude de faire. Même les activités essentielles me sont difficiles à réaliser. Je suis handicapé. |
| 6. J'ai arrêté de travailler depuis 1 an ou plus et/ou je touche une indemnisation à cause de mes problèmes de vertiges ou déséquilibre. |

3/ Every options have been explored ?



1 /Evaluation of anterior treatments «classical»

-Bétahistine, Méclozine ,Flunarizine, Acétyl-leucine

-Oral steroids

-Osmotic treatments: diuretics (Acétazolamide ,Furosémide), (Glycérol)

2 /If any doubt do not hesitate testing migraine prophylactic treatment

Flunarizine , Propanolol 40 to 80 mg , Amitriptylline ,Vérapamil

3 /If emotional context: reinsurance, explanation, BCT, relaxation therapy, etc.

ITI CORTICOSTEROIDS

We know :

- 1/ Glucocorticoids receptors existing présents at cochlea level, vestibular and spiral ligament
- 2/ Auto-immuns complexes have been identified at endolymphatic sac level (IgG deposit, antibodies anticollagene type II and endolymphatic bag)
- 3/ Aquaporins (transmembrane proteins) have been identified in the utricle, are sensitive to glucocorticoids
- 4/
- 5/ Few randomized clinical trials have highlighted significant effect with 2 years follow-up compared to placebo.
- 6/ Most used concentration is 4mg/ml 1ITI/day with a 3 to 5 ITT blocks (DEXA)
- 7/ Alternative option methylprednisolone at 67,5 mg 2 to 3 ITT according to literature

Glucocorticoids stimulate endolymphatic water reabsorption in inner ear through aquaporin 3 regulation.

Nevoux J, et al. Pflugers Arch. 2015.
[Show full citation](#)

Review

Intratympanic corticosteroids in Ménière's disease: A mini-review

Mitesh Patel

Division of Brain Sciences, Imperial College London, Charing Cross Hospital, London, W6 8RF, UK

Received 9 April 2017; revised 27 May 2017; accepted 1 June 2017

Table 1

Summary of studies meeting inclusion criteria on the effectiveness of intratympanic steroid injections in Ménière's disease over 2-years. Class A (complete) vertigo control was used as the primary outcome in this Review.

Study	Steroid type	Conc. (mg/ml)	Treatment protocol	Further injections offered 'as-needed'	Study type	Sample size for steroid arm	Percentage of patients with Class A vertigo control (%)
Barrs, 2004	Dex	10	1 injection for 4 consecutive weeks	Yes	Retrospective	34	24
Garduno-Anaya et al., 2005	Dex	4	1 injection daily for 5 consecutive days	No	Prospective	11	82
Boleas-Aguirre et al., 2008	Dex	12	1 injection	Yes	Retrospective	129	91 ^a
Herraiz et al., 2010	Methylpred	40	1 injection for 3 consecutive days	Yes	Prospective	29	78
Casani et al., 2012	Dex	4	1 injection over 3 consecutive days	Yes	Prospective	28	43
Martin-Sanz et al., 2013a	Dex	4	1 injection weekly for 3 consecutive weeks	No	Prospective	53	15.1
Martin-Sanz et al., 2013b	Dex	4	1 injection daily for 3 consecutive days or 1 injection for 3 consecutive weeks	No	Retrospective	22/34	40.9/44.1
McRackan et al., 2014	Dex	24	1 injection, 3 doses delivered 10 min s apart	Yes	Retrospective	159	81.1 ^b
She et al., 2015	Methylpred	20	1 injection over 10 consecutive days	No	Retrospective	16	81
Albu et al., 2016	Dex	4	1 injection over 3 consecutive days or 1 injection over 3 consecutive days + high-dose betahistine	Yes	Prospective	32/30	44/73.3
Patel et al., 2016	Methylpred	62.5	1 injection fortnightly (1 course = 2 injections)	Yes	Prospective	30	70
Leng et al., 2017	Dex	5	1 injection for 4 consecutive days, over 4 consecutive weeks	Yes	Retrospective	23	73.9

Dex = Dexamethasone; Methylpred = Methylprednisolone.

Review

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5. Conclusion

If Meniere's disease patients continue to experience attacks of vertigo despite dietary management or oral medication, intratympanic steroid may be used as an as-needed therapy.

With steroid, there is little risk of hearing loss, chronic symptoms of dizziness resulting from the fixed vestibular loss or adverse events. As many patients with Ménière's disease are frail or experience anxiety that complicates ablative therapy, intratympanic steroid is an excellent option. That said, clinicians must decide the appropriate treatment in concordance with the patient's expectation as intratympanic steroid treatment may need to be repeated periodically.

ITI Gentamicin



- 1 / **Ototoxic effect:** induce a stable and constant deficit allowing vestibular centers to compensate the deficit
- 2 / Effect on **vertigo long term management has been demonstrated** (numerous publications and meta-analyzes) 75 to 90 % of vertigo control
- 3 / **Low hearing impact risk**, with low dose protocole remains (no consensus).
- 4/ **Compensation difficulties** regarding vestibular deficit induced by ITI of gentamicin have to be taken into consideration.
- Which protocol ?



To be used according to well defined criteria

Intratympanic (IT) Therapies for Menière's Disease: Some Consensus Among the Confusion

Desi P. Schoo¹ · Grace X. Tan¹ · Matthew R. Ehrenburg¹ · Seth E. Pross¹ ·
Bryan K. Ward¹ · John P. Carey¹

ITT of Gentamicin: Fine vertigo control (85 to 90% of the time) with moderate risk for audition with 'low dose' protocols or via titration and spaced ITT, however the risk does exist.

ITT of Corticoids: Lack of consensus, various protocols and very variable results.

Randomized studies Gentamicin/Corticosteroids

108 articles analyzed

ITI in MENIERE disease

Dexamethason versus Placebo

- *Garduño-Anaya et al., 2005* Prospective, randomized
Open, n = 22, follow-up 2 yrs Vertigo CC* Dexa: 82% / placebo: 57%
THI Tinnitus Dexa: 48% / Placebo: 20%

Steroids vs Gentamicin

- *Gabra et Saliba, 2013* Retrospective
n = 89, follow-up 2 yrs Vertigo CC* Genta: 87% / MéthylP: 48%
PAM: No différence Genta / MéthylP
- *Patel et al., 2016* Prospective, randomized
Dble aveugle, n = 60 2yrs Vertigo CC* Genta : 87%
Vertigo CC* MéthylP : 90% (20% réinjection)
PTA : No différence Genta / MéthylP
- *Casani et al., 2012* Prospective, randomized
Open, n = 60 Vertigo CC* Genta : 93% / Dexa : 61%
PTA : No différence Genta / Dexa

CC : complete vertigo control AAO-HNS criteria ; **CC*** : idem, classe A + B ; **PTA** : Pure tone audiometry
Dexa : Dexamethasone ; **MéthyIP** : Methylprednisolone

Objectives: To evaluate outcomes of intratympanic (IT) dexamethasone and gentamicin in Ménière Disease (MD).

Methods: Charts of adult patients with unilateral definite MD receiving IT gentamicin or dexamethasone from January 2000 to December 2011 were retrospectively reviewed. All patients had at least 6 months follow-up. Failure in each group was defined as failure to respond to three injections or need for more aggressive therapy.

From January 2000 to December 2009, all patients received IT gentamicin, administered as primary therapy after failure of conservative treatment. Gentamicin was administered every 2 weeks, up to three injections, until vertigo control was achieved. From January 2010 to December 2011, the treatment protocol shifted to IT dexamethasone as initial treatment, with gentamicin used for dexamethasone failures. Dexamethasone was administered weekly for up to three injections. Treatments could be repeated if symptoms recurred.

Results: Thirty-three patients received IT dexamethasone, and 70 patients received IT gentamicin. Dexamethasone patients received a mean of 3.3 injections compared to 2.7 in the gentamicin group ($P = 0.011$). There were 12 (36%) dexamethasone group and only seven (10%) gentamicin failures ($P = 0.025$). No patients failed both treatments. Mean time to failure in the dexamethasone group was 5 months, whereas in the gentamicin group it was 27 months. Mean pure tone average and speech discrimination scores at baseline and 6 months post-treatment were similar between groups.

Conclusion: Subjects receiving IT gentamicin required fewer injections and had a significantly longer time to failure than those receiving dexamethasone. Audiometric outcomes were similar between the groups. The use of IT gentamicin as initial treatment for MD is safe and effective.

Key Words: Ménière disease, gentamicin, intratympanic therapy.

Level of Evidence: 3



Take home message



- Some are fond of gentamicin ‘ low dose ‘ because results on vertigos are better and more lasting in time.
- Current tendency is to propose ITI Steroids in the first place since recent studies.
- To ponderate with experience:
 - - Dexa is a good option to wait for another stage, however most of the time the disease keeps evolving and reinfections are required. (*how often ? When should we consider the treatment as a failure ?*)
 - - Genta most of the time « stops » the disease with stable vertigo and deafness results but is destructive for the vestibule and demonstrates a very low but existing risk for audition.
- *Has to be well explained to the patient*

In practice



Conservative treatment : Dexamethasone

- If Deafness with a PTA < 50 dB
- If low or no vestibular deficit to caloric tests (<50%)
- If hearing loss or high vestibular deficit on contralateral ear.
- For all patients suspected with low vestibular compensation (elderly patients)
- If Meniere and vestibular migraine entangled +++++

Ablative treatment : Gentamicin

in other cases and when the handicap is severe .discussion is required

Ablative solution with gentamicin



1/ ITT of gentamicin 1st to be considered:

- If Tumarkin attacks
- If PTA and/or severe vestibular deficit with a regular contralateral ear and Meniere disease diagnosis defined and patient highly disabled with no other signs that could interfere with compensation.

-2/ ITT de gentamicin 2nd to be considered:

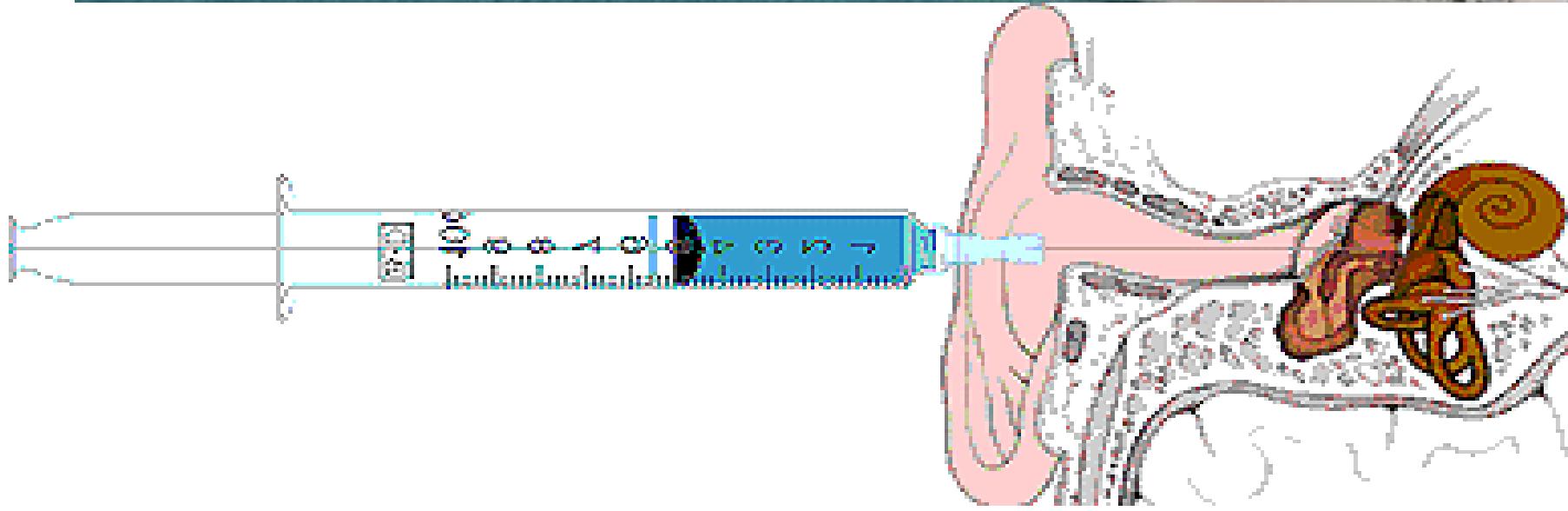
- If failure of the ITT of dexamethasone

➤ The patient has to be informed that the potential vestibular deficit creates post-treatment instability which implies a required vestibular reeducation.

ITI Dexamethasone

- Under microscope, posterior mesotympanic injection with a spinal needle of 25 GA (0,50x90mm) and a syringe of 1ml
- Ambulatory treatment under local anesthesia (prilocaine)
- Dexamethasone 4mg/ml 0,4 to 0,6 ml per injection
- An injection per day for 3 days
- The patient has to remain lying down in lateral decubitus for 40 minutes after injection.
- Systematic control at 3, 6 12 and 24 months.

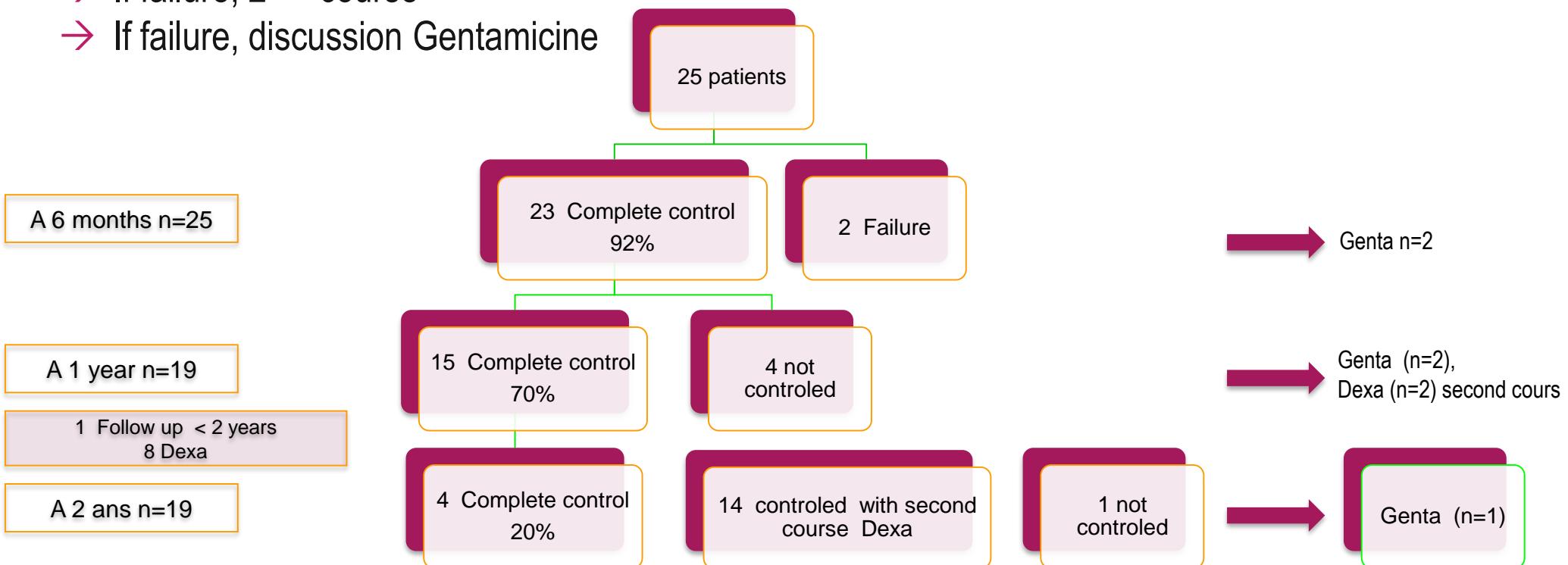




ITI Dexaméthasone : Results

Evaluation at 3, 6 & 12 months

- If failure, 2^{ème} course
- If failure, discussion Gentamicine



ITI Dexamethasone: Results

Original article

Control of vertigo in Ménière's disease by intratympanic dexamethasone

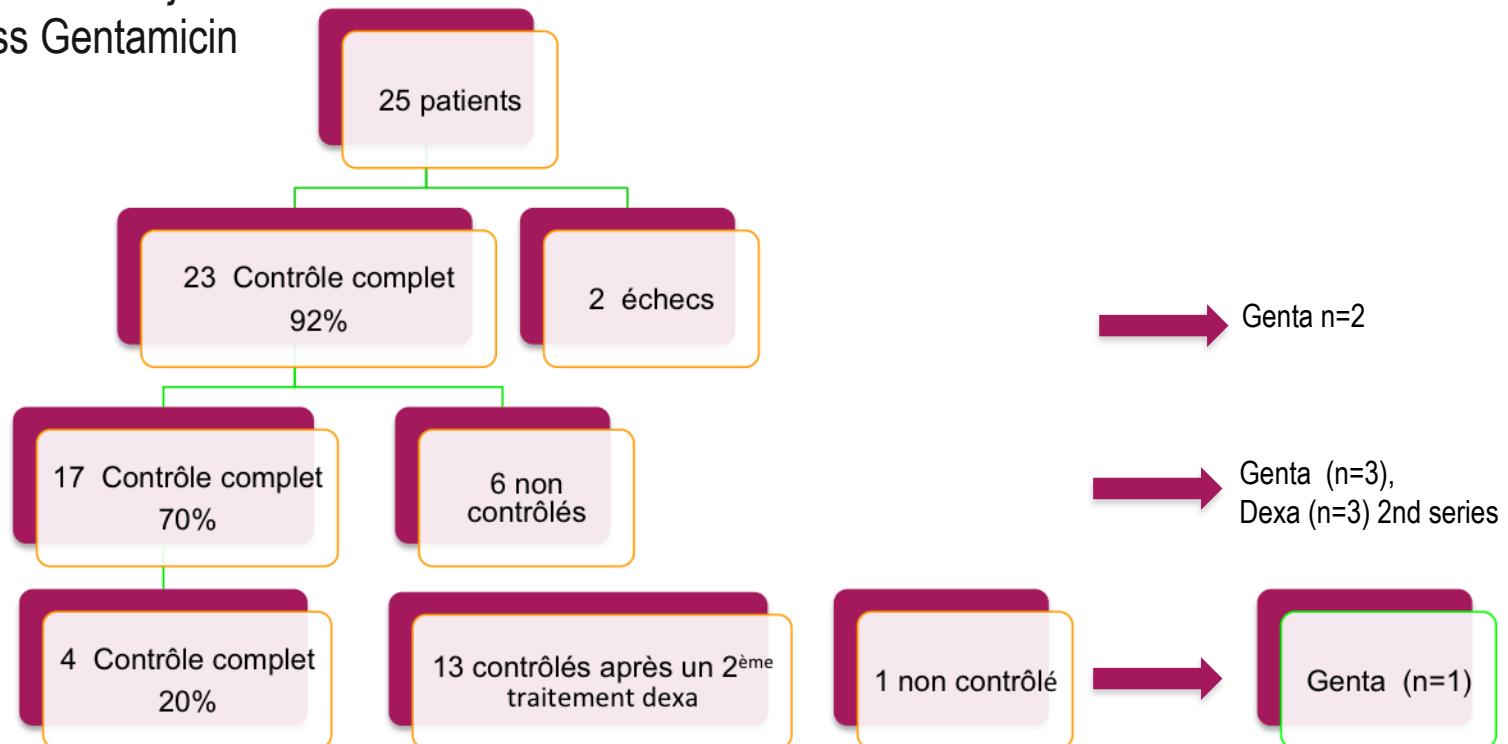
A. Weckel*, M. Marx, M.-J. Esteve-Frayssse

Service ORL, CHU Purpan, place Baylac, 31059 Toulouse cedex 9, France

Evaluation at 6, 12 and 24 months

- If vertigos remain, 2nd series of injection
- If vertigos persist, discuss Gentamicin injections

At 6 months n=25



ITI Dexamethasone synthesis

25 patients

- With only Initial treatment

Vertigo Control class A : **92% at 6 months (n=25)**

70% at 1 year (n=20)

20% at 2 years (n= 19)

- After one or 2 re-injections **56 % patients more controlled at 2 years in total 76%**

- 24% of patients had ITI of Gentamicine during this time

ITI Gentamicin

- Gentamicin concentration 40mg/ml, 0,4 to 0,6 ml for each ITI
- Dose to be injected?

Outcomes of intratympanic Gentamicin injection to treat Meniere's disease Leh-Kiong-Hun 2012, Otol Neurotol

- 13,4 mg total dose injected, low threshold under which results are significantly less efficient toward vertigos control.
- 1 ITI at 40 mg/ml should be of at least 0,4 to 0,5 cc to be considered efficient



CURRENT PROTOCOL

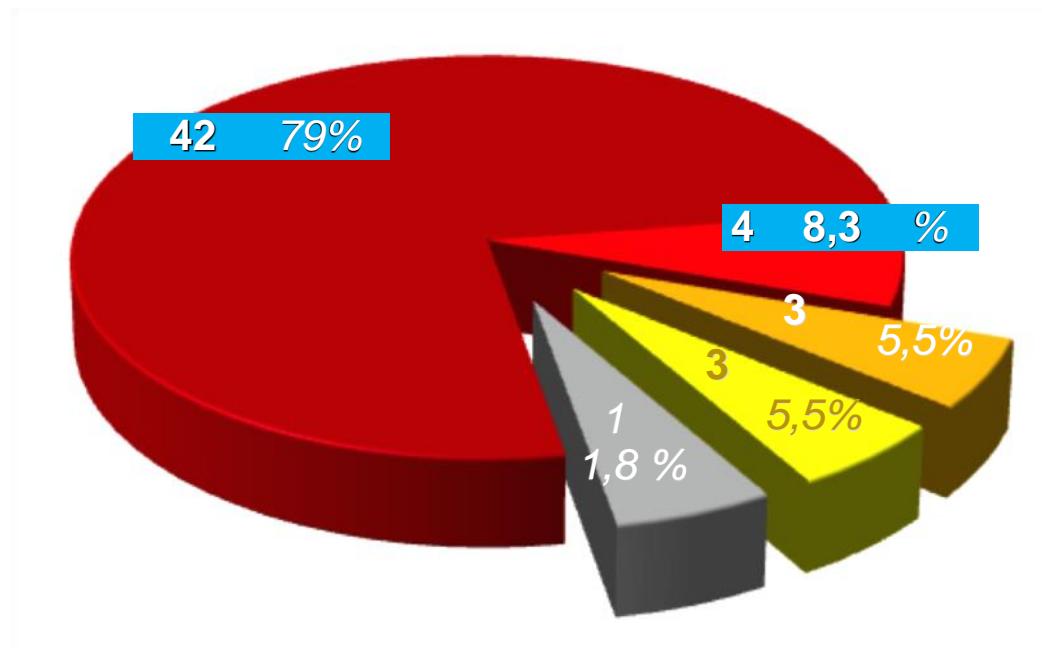
MIXT PROTOCOL: low dose/Titration

- 1 injection → control between J21 and J30. If:
 - Clinical signs new vestibular deficit
 - No new crisis
 - Deficit \geq 75 to 80 % on caloric test
 - and control at 3, 6, 12, 24 months with audiology, caloric test, VHIT and PEMV
 - If new crisis → 2nd course of ITI with same protocol.
- } STOP injections if 2 or 3 criterion

Vertigo Control (Criteria AAO-HNS)

53 patients

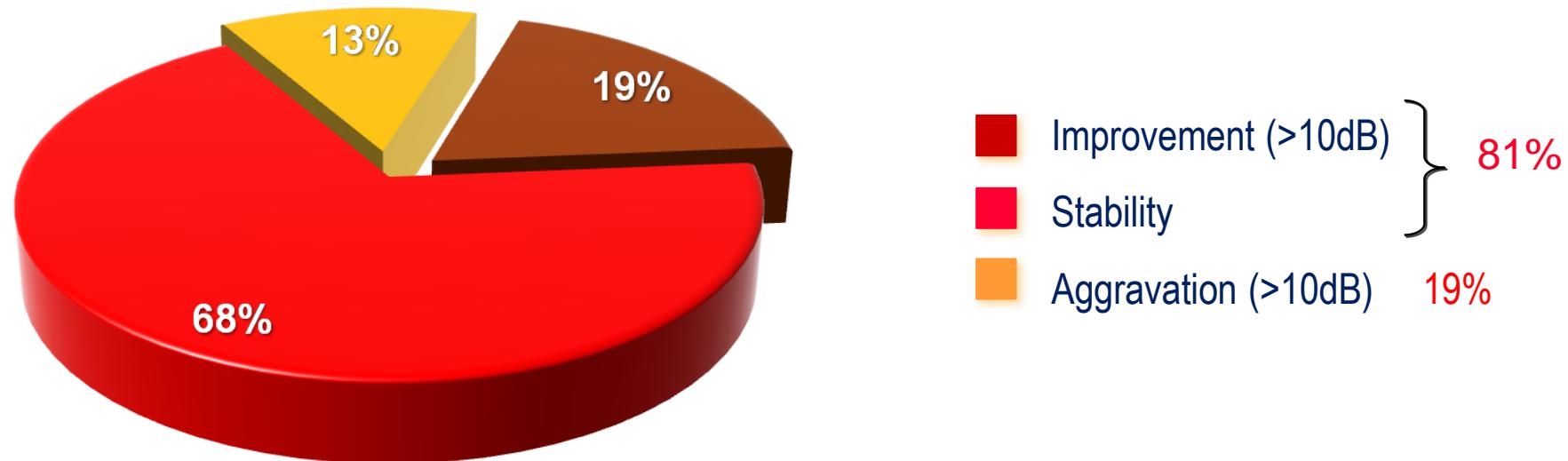
■ Mean follow-up: 76 months



- Classe A: Complete control 79% } 87%
- Classe B: Substantial control 8%
- Classe C: Partial control 6%
- Classe D: no change 5%
- Loss track 1 patient

Hearing results

53 patients

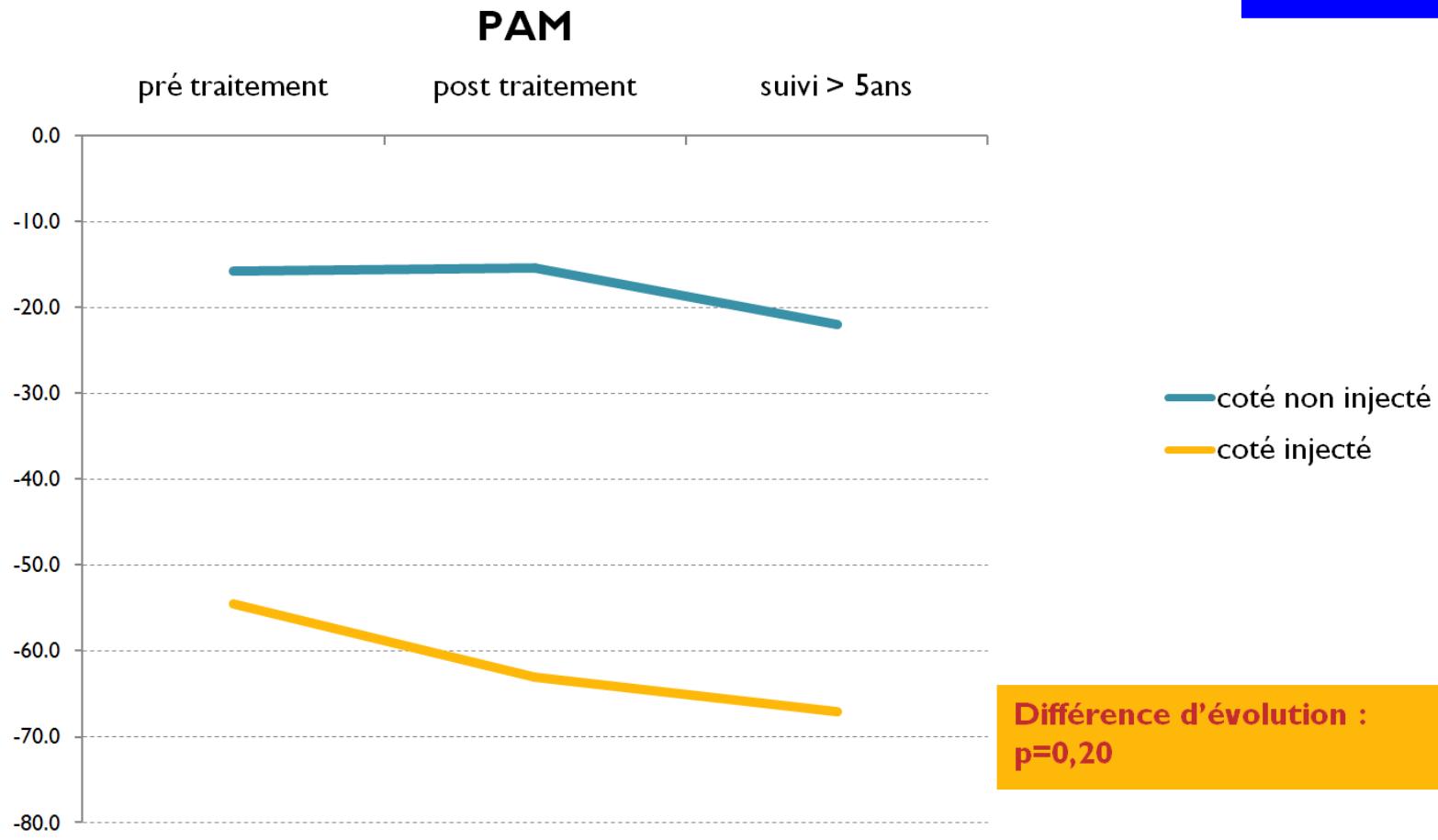


Improvement average: 26 dB (13 to 40 dB)
Aggravation average: 21dB (14 to 29 dB)
No complete or deep deafness observe

Hearing evolution at 5 years compared to contra lateral hearing

C.Tavernier

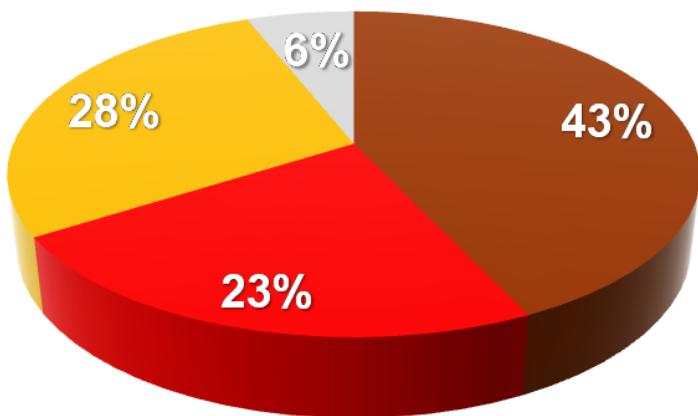
32 patients



INSTABILITY (EVS)

53 patients

- Average follow-up: 76 months



- 0: no instability
- 1: moderate instability with no handicap
- 2: moderate instability but light handicap
- 3: instability with fallings when walking or changing position
- 4: instability leading to falling as soon as the patient stands
- Non available data

66%

No significant statistical deviation as a function of the injection protocol ($p=0,57$)

A vestibular reeducation is most of the time required

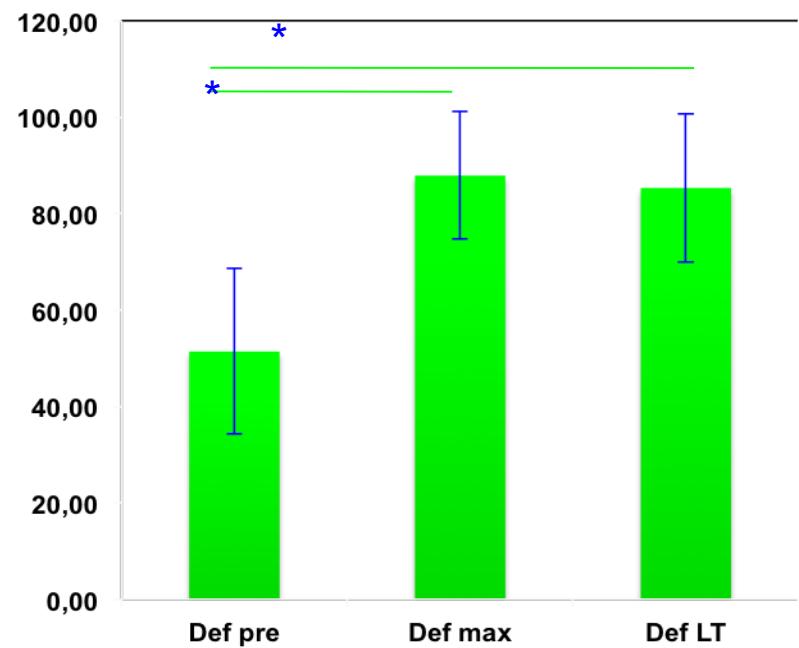
Long-term Vertigo Control and Vestibular Function After Low-dose On-demand Transtympanic Gentamicin for Refractory Menière's Disease

Nicolas, Sarah*; Kmeid, Michel*; Mansour, Charles*; Fraysse, Bernard*; Deguine, Olivier*, Marx, Mathieu*; Esteve Fraysse, Marie-José
Otology & Neurotology: February 2019 - Volume 40 - Issue 2 - p 218–225

- Average follow-up 4,8 years (from 2 to 8 years) retrospective
- Vestibular average deficit over caloric test:

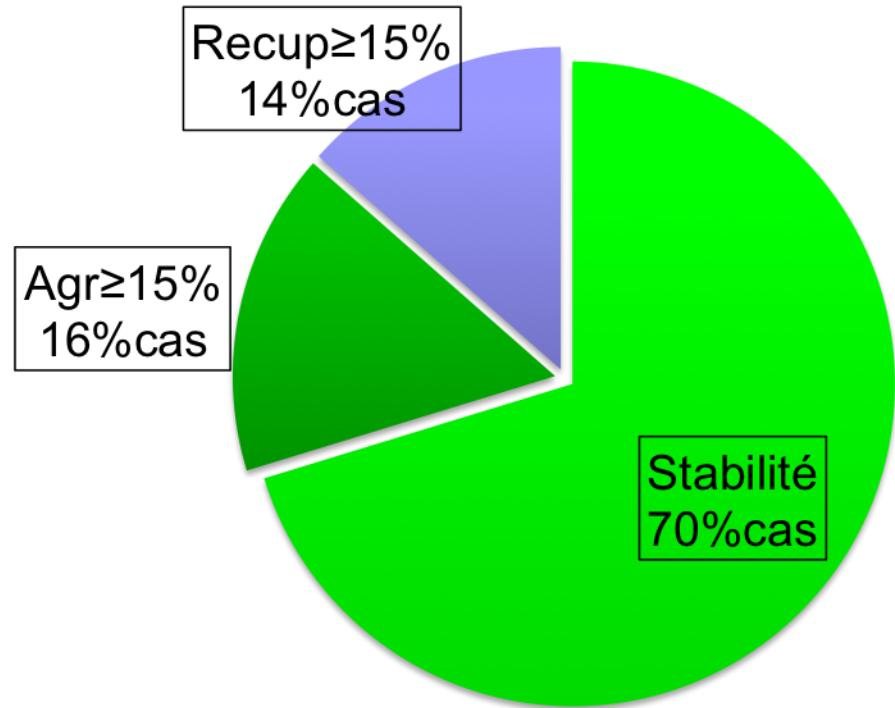
- Pre-treatment deficit = 51,4 (SD = 17)
- Maximum deficit = 87,9 (SD = 13)
- Long term deficit = 85,3 (SD = 15)

➡ Vestibular deficit is increased post ITI of gentamicin and remains stable during the long term follow up

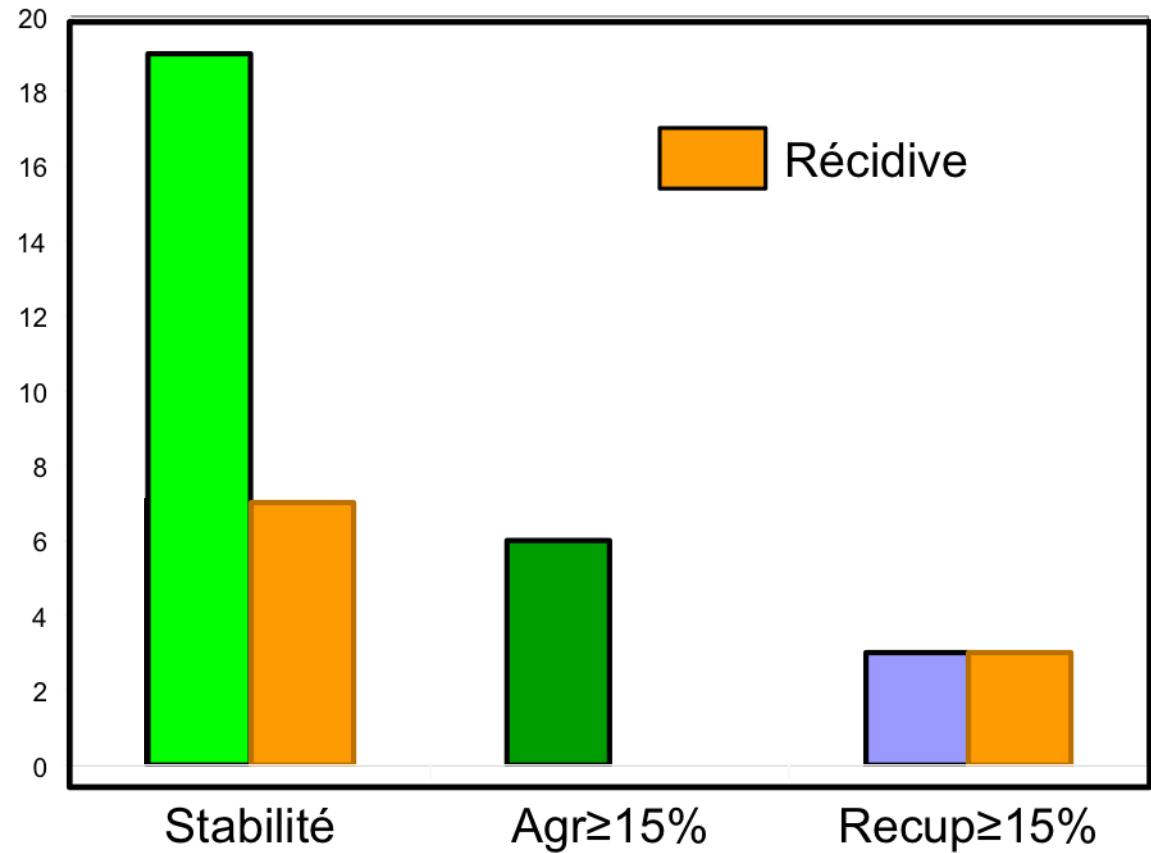


Def pre : pre-treatment deficit; Def max : maximum deficit;
Def LT : long term deficit
* : significant variation

Correlation between vertigo recurrence / caloric tests variations over time

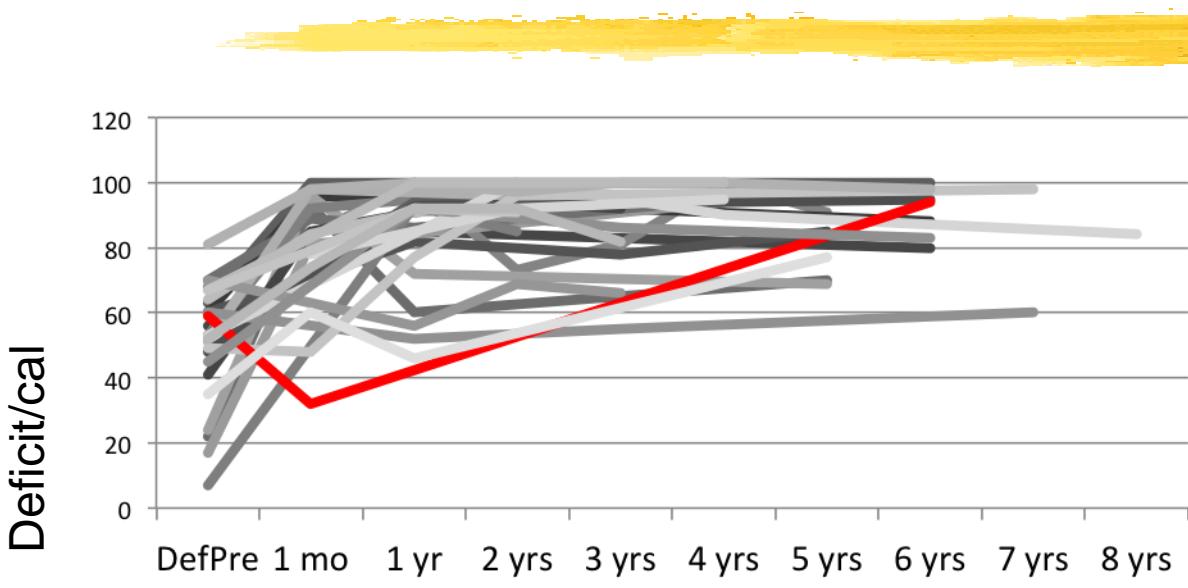


Caloric tests over time

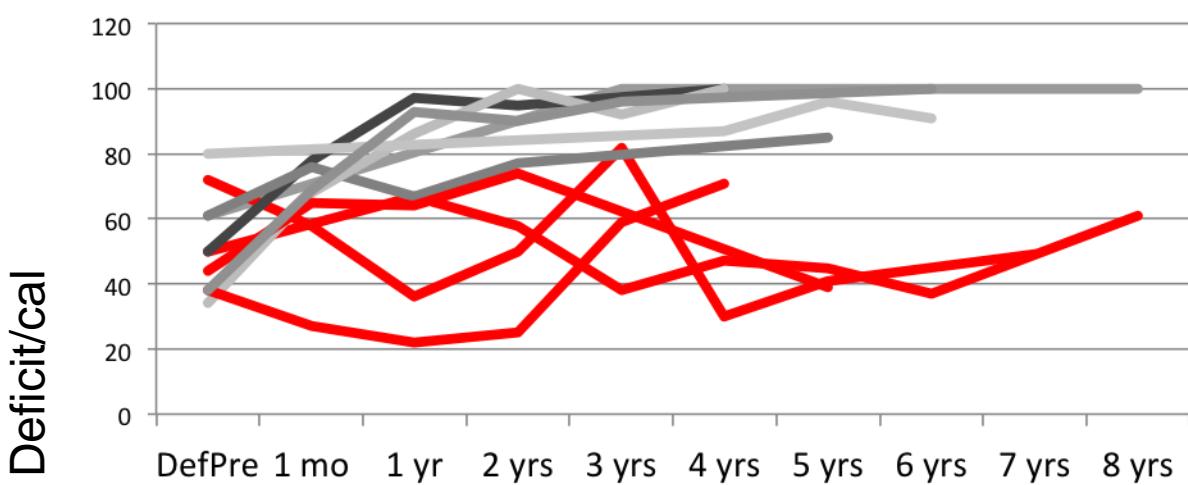


Correlation between vertigos recurrence / caloric tests variations over time

Results: evolutive profiles



■ « Successful » group stable
and deep deficit > 80%



■ « Recurrence » group
4/10 patients with fluctuant and
average deficit

Take home message / ITI Ménière's disease



- 1/ Menière disease and vestibular migraine can often coexist. Warning !
- 2/a Dexamethasone is the treatment to be considered in the first place especially if the hearing is preserved (1 to 2 blocks of 3 ITI each);
- 2/b If recurrence in time provided after intermediate period of good results, ITI can be renewed (« as needed » protocol to be discussed with patient versus ITI of Genta)
- 3/ It's important that caloric tests and VHT are achieved before ITI in order to evaluate vestibular status with both ears.
- 4/ Gentamicin protocols low dose are efficient with no risks, especially no major hearing risk. (PTA>40dB)
- 5/ A vestibular rehabilitation has to be proposed post ITT of Gentamicin

TAKE HOME MESSAGE



- 6/ If recurrences with Gentamicin, reevaluate the vestibular function with caloric tests
 - It is an option to reinject gentamicin.
-
- 7/ In the reinjection case, PTA remains stable if low dose gentamicin protocol is thoroughly followed.
-
- 8/ It's crucial to inform the patient on its treatment options, risks and long-term follow-up.



Thanks for your attention

If you have any questions ?

You can contact me at :

fraysse.mj@chu-toulouse.fr
estevefraysse@yahoo.fr

Take home message

- La Migraine vestibulaire n'est pas une indication d'ITT.
- Si MV et MM associées essayer d'abord les ttt de la Migraine vestibulaire.
- Si MV et MM associés et échec des ttt : attention à la Gentamicine car risque de bi latéralisation. Préférez les ITT de corticoïdes si les signes de Maladie de Ménière sont prédominants.



Indispensable de bien connaître les critères Dc actuels de la Barany society
des 2 maladies ++++