Novel treatments for syncope

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Mechanisms of syncope

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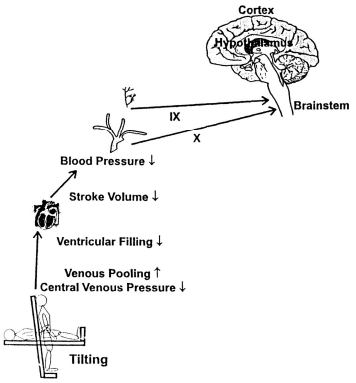
Neurohumoral responses to orthostatic stress.



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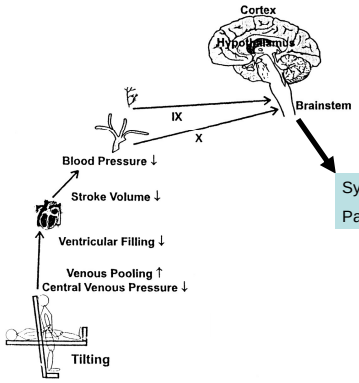
Neurohumoral responses to orthostatic stress.



Sympathetic activation
Parasym withdrawal

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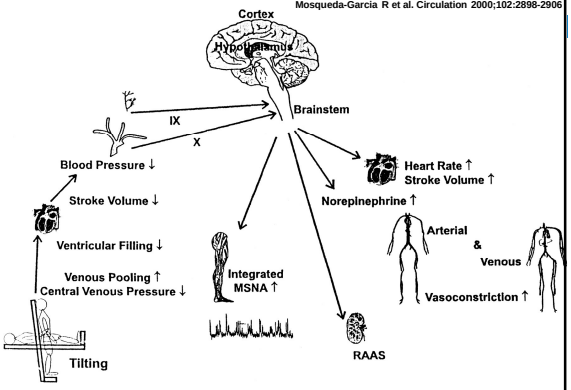
Neurohumoral responses to orthostatic stress.

Mosqueda-Garcia R et al. Circulation 2000;102:2898-2906



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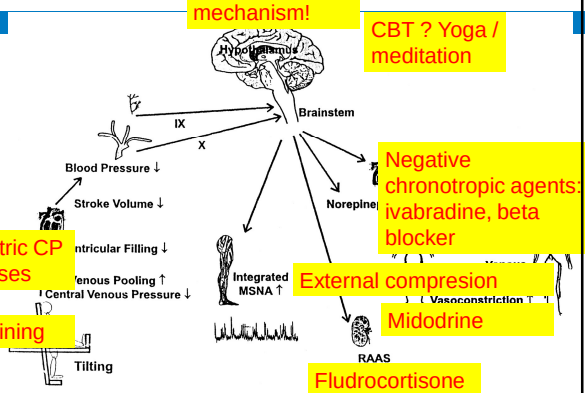
Treatment of syncope based on mechanism

Understanding mechanism!

CBT ? Yoga / meditation



Negative chronotropic agents: ivabradine, beta blocker

Isometric CP exercises

External compresion

Tilt training

Midodrine

Fludrocortisone

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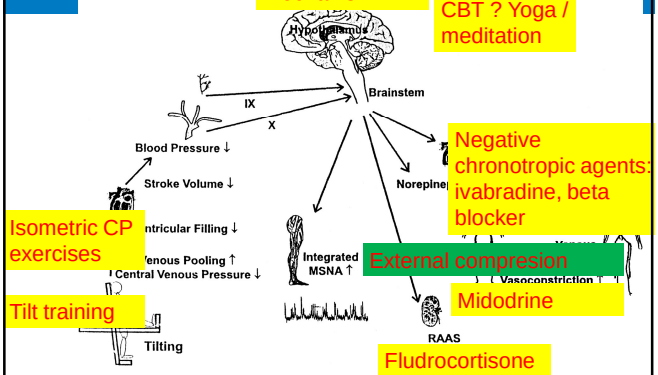

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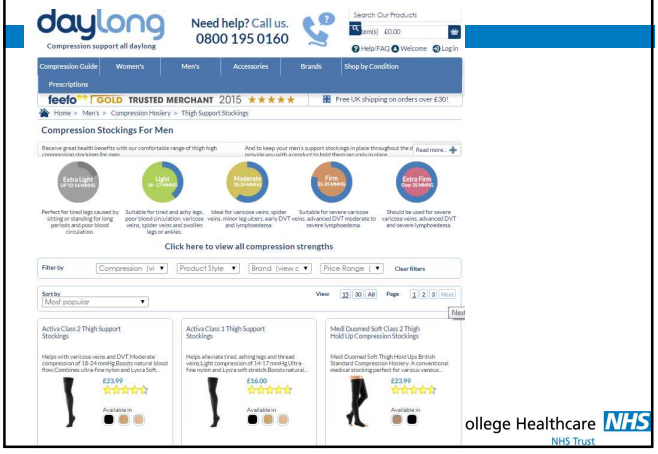
Compression – what to advise?



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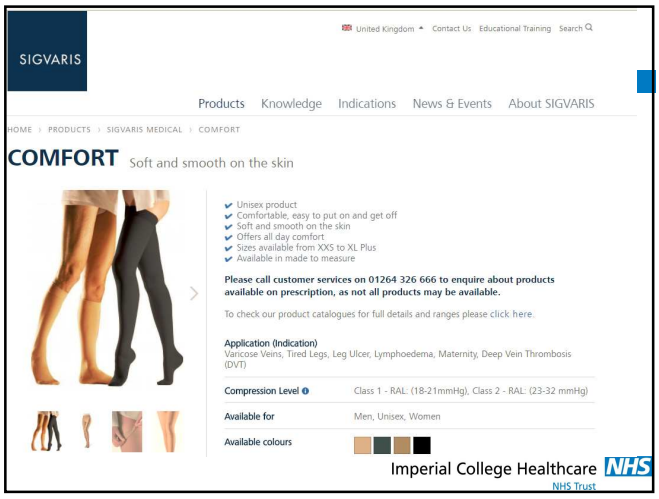

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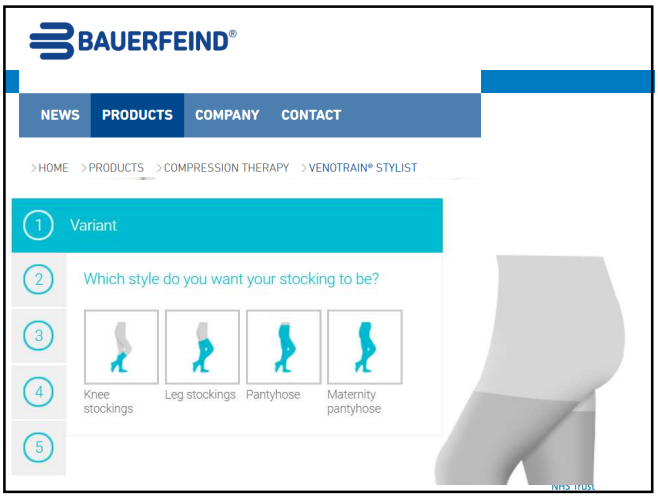

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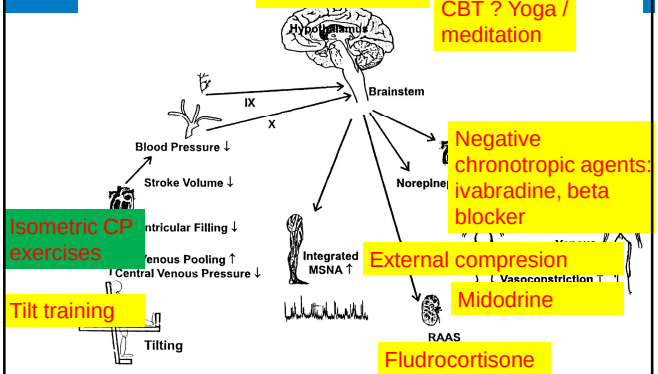

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Isometric counter-pressure exercises

Management of Vasovagal Syncope

Controlling or Aborting Faints by Leg Crossing and Muscle Tensing

C.T. Paul Krediet, BS; Nynke van Dijk, MS; Mark Linzer, MD; Johannes J. van Lieshout, MD, PhD; Wouter Wieling, MD, PhD

Background—Posture-related vasovagal syncope is by far the most frequent cause of transient loss of consciousness, and present pharmacological and cardiac pacing treatment remains unsatisfactory. A simple maneuver to prevent or diminish vasovagal reactions would be beneficial.

Methods and Results—Twenty-one patients with recurrent syncope (age 17 to 74 years, 11 males) who were referred for routine tilt-table testing and had a positive test were included. They were instructed to perform leg crossing and muscle tensing for at least 30 seconds at the onset of a tilt table–provoked impending faint. Continuously measured blood pressure and heart rate at nadir and during the maneuver were compared. Ten months after the test, a telephone follow-up was performed. The physical counter-maneuver, performed in 20 of 21 subjects, increased blood pressure and heart rate. Systolic blood pressure rose from 65±13 to 106±16 mm Hg (mean±SD, $P<0.001$), and diastolic blood pressure rose from 43±9 to 65±10 mm Hg ($P<0.001$). During the maneuver, prodromal symptoms disappeared in all patients, and none lost consciousness. After terminating the maneuver, symptoms did not return in 5 subjects during the test. At follow-up, 13 of 20 patients reported that they applied the maneuver in daily life and benefited from it.

Conclusions—Leg crossing combined with tensing muscles at the onset of prodromal symptoms can postpone and in some subjects prevent vasovagal syncope. (*Circulation*. 2002;106:1684-1689.)

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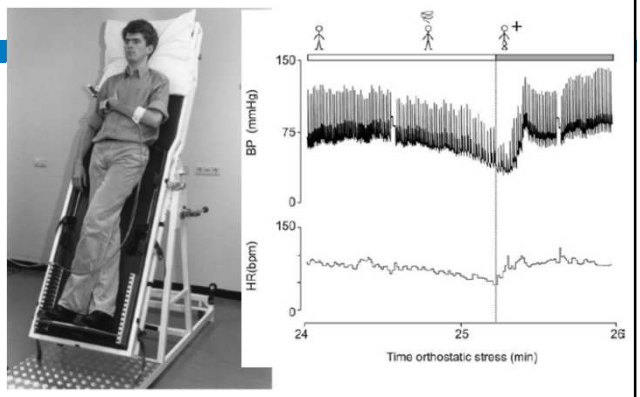

Figure 1. Leg crossing and muscle tensing during tilt-table testing. The maneuver consists of crossing the legs in standing position with tensing of leg, abdominal, and buttock muscles. The legs are thus firmly squeezed together (person is a stand-in).

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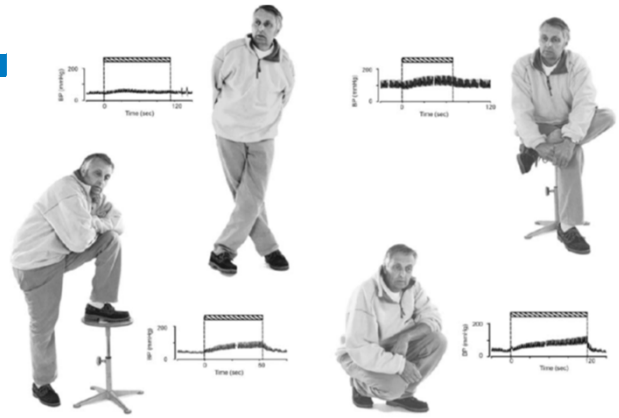

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Effectiveness of Physical Counterpressure Maneuvers in Preventing Vasovagal Syncope

The Physical Counterpressure Manoeuvres Trial (PC-Trial)

Nynke van Dijk, MD,* Fabio Quartieri, MD,† Jean-Jaques Blanc, MD,‡ Roberto Garcia-Civera, MD,§ Michele Brignole, MD,‖ Angel Moya, MD,¶ Wouter Wieling, MD, PhD,*
on behalf of the PC-Trial Investigators

We performed a multicenter, prospective, randomized clinical trial, which included 223 patients age 38.6 (±15.4) years with recurrent vasovagal syncope and recognizable prodromal symptoms. One hundred and seventeen patients were randomized to standardized conventional therapy alone, and 106 patients received conventional therapy plus training in PCM. The median yearly syncope burden during follow-up was significantly lower in the group trained in PCM than in the control group ($p = 0.004$). During a mean follow-up period of 14 months, overall 50.9% of the patients with conventional treatment and 31.6% of the patients trained in PCM experienced a syncopal recurrence ($p = 0.005$). Actuarial recurrence-free survival was better in the treatment group (log-rank $p = 0.018$), resulting in a relative risk reduction of 39% (95% confidence interval, 11% to 53%). No adverse events were reported.

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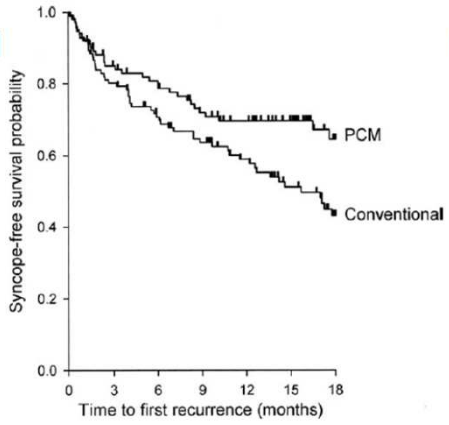

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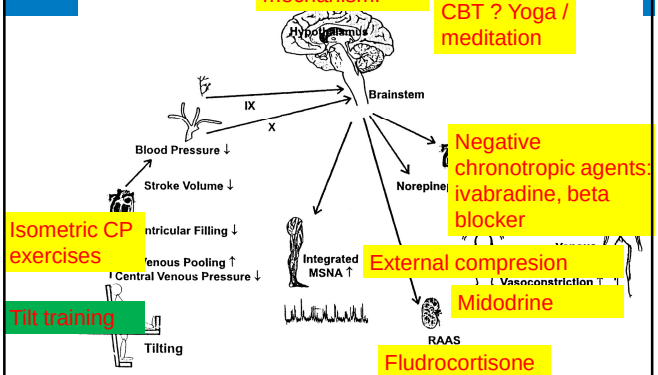
Treatment of syncope based on mechanism

Understanding mechanism!

CBT ? Yoga / meditation



Negative chronotropic agents: ivabradine, beta blocker

Isometric CP exercises

External compresion

Tilt training

Midodrine

Fludrocortisone

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Tilt Training: A New Treatment for Recurrent Neurocardiogenic Syncope and Severe Orthostatic Intolerance

HUGO ECTOR[1], TONY REYBROUCK[2,3], HEIN HEIDBÜCHEL[1], MARC GEWILLIG[2], FRANS VAN DE WERF[1]

From the Departments of Cardiology[1], Pediatric Cardiology[2] and Cardiovascular Rehabilitation[3], University Hospital Gasthuisberg, Leuven, Belgium

ECTOR H., ET AL.: Tilt Training: A New Treatment for Recurrent Neurocardiogenic Syncope and Severe Orthostatic Intolerance. *Medical treatment of neurocardiogenic syncope is insufficient in many cases. We have observed a therapeutic effect of repeated head-up tilt testing. Therefore, we have started a program of tilt training for heavily symptomatic patients. After hospital admission, they were tilted daily (60° inclination) until syncope, or until a duration of 45-90 minutes (90 sessions in 13 patients). The mean tilt tolerance, at the first diagnostic head-up tilt table test, was 22.3 minutes (st. dev. 10.9). Before hospital discharge, 12/13 patients could sustain the full duration of tilt table testing without any symptom. In one patient syncope persisted. The patients were instructed to continue a program of daily tilt training at home, by standing against a wall for 30 minutes, one or two times per day. This resulted in a complete disappearance of syncope in all 13 patients.*
Orthostatic intolerance and the excessive autonomic reflex activity of neurocardiogenic syncope can be remedied by a program of continued tilt training, without the administration of drugs.

syncope, orthostatic intolerance, tilt table, tilt training

PACE 1998

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Tilt Training for Recurrent Neurocardiogenic Syncope

Effectiveness, Patient Compliance, and Scheduling the Frequency of Training Sessions

Ozan Kinay,[1] MD, Mehmet Yazici,[3] MD, Cem Nazli,[1] MD, Gurkan Acar,[2] MD, Omer Gedikli,[2] MD, Ahmet Altinbas,[2] MD, Halil Kahraman,[2] MD, Abdullah Dogan,[2] MD, Mehmet Ozaydin,[2] MD, Nurullah Tuzun,[2] MD, *and* Oktay Ergene,[2] MD

SUMMARY

Unsatisfactory results obtained with medical therapy and dual-chamber pacing for prevention of recurrent neurocardiogenic syncope necessitated the development of new treatment modalities. Tilt-training, a novel treatment for recurrent neurocardiogenic syncope based on exercise sessions with prolonged upright posture (either on a tilt-table or standing on foot against a wall), was shown to be effective in preventing the recurrence of neurocardiogenic syncope. The purpose of this study was to demonstrate the long-term beneficial effects of a transient tilt training program lasting 2 months.

Thirty-two patients with recurrent neurocardiogenic syncope (mean number of syncope episodes in the last 6 months was 3.4 ± 2.3) constituted the study group. All of the patients were tilt test positive. The patients were taught a tilt training program with 2 phases (in-hospital training with repeated tilt procedures until 3 consecutive negative results were obtained and home exercises with standing against a wall) and home exercises lasted a maximum of 2 months. After this training program, the patients received no treatment and were followed for the recurrence of syncope. At the end of the follow-up period (376 ± 45 days), 81% of the patients were free of recurrent syncope.

This study revealed that similar successful results can also be obtained with a transient tilt training program as a first line treatment strategy. Less interference with the daily activities of the patients is the major advantage of this strategy. The ease of performance and high effectiveness rate will most likely result in more frequent utilization of this treatment modality. (*Jpn Heart J* 2004; 45: 833-843)

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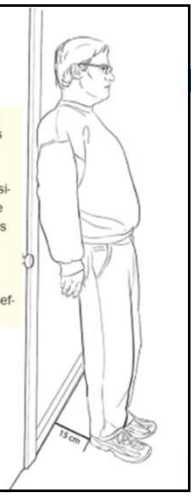
Tilt training

Schematic illustrating the "tilt-training" technique for home use. Patients are instructed to stand and place only the upper back against a wall (with ankles approximately 15 cm away from the wall) without moving. The sessions are initially performed in a quiet and comfortable environment (possibly under supervision of a family member). The patient stands still with upper back positioned lightly against a wall or a corner. A carpeted floor is preferred, and the nearby environment should be devoid of sharp-edged objects or other hazards should the patient fall. Initially we recommend 3 to 5 min of standing twice daily. Then, depending on symptom status, the duration can be slowly increased each week. The target is 20 to 30 min twice daily without symptoms. Thereafter, 20 min sessions 3 to 4 times/week are recommended indefinitely. Figure illustration by Rob Flewell.



Benditt JACC 2008: Syncope – therapeutic approaches: State of the art

Imp

How to prescribe tilt training ?

Goal is to enhance neurovascular response to standing

Standing training for progressively longer periods of time over 12 weeks.

Start slow : 3-5 mins bd,
Aim to achieve 30-40min bd

Non-randomised trial data suggest reduces susceptibility

Limitations:
1. Motivation
2. No randomised trials
3. Patient selection – who is suitable for this program?

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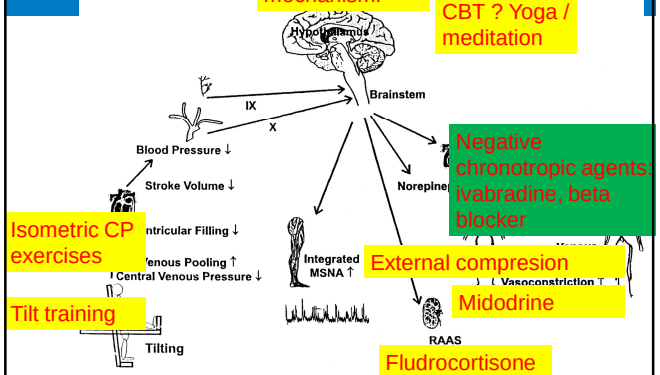
Treatment of syncope based on mechanism

Understanding mechanism!

CBT ? Yoga / meditation



Negative chronotropic agents: ivabradine, beta blocker

Isometric CP exercises

External compresion

Tilt training

Midodrine

Fludrocortisone

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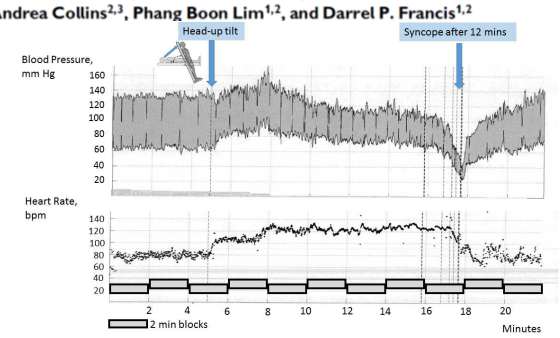
Ivabradine in treatment of sinus tachycardia mediated vasovagal syncope

Richard Sutton[1,2*], Tushar V. Salukhe[2,3], Ann-Christine Franzen-Mcmanus[2,3], Andrea Collins[2,3], Phang Boon Lim[1,2], and Darrel P. Francis[1,2]



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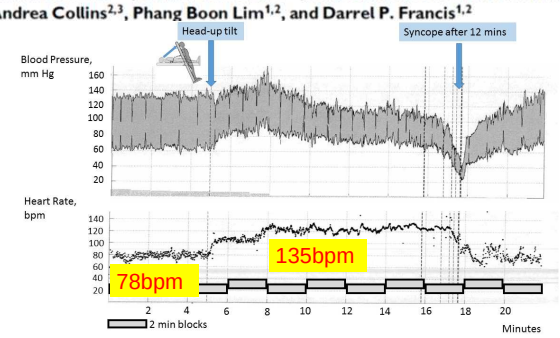
Ivabradine in treatment of sinus tachycardia mediated vasovagal syncope

Richard Sutton[1,2*], Tushar V. Salukhe[2,3], Ann-Christine Franzen-Mcmanus[2,3], Andrea Collins[2,3], Phang Boon Lim[1,2], and Darrel P. Francis[1,2]



Ivabradine, an I(f) current blocker, has shown promising results in treatment of postural orthostatic tachycardia syndrome (POTS). There is a subgroup of vasovagal syncope (VVS) patients, who demonstrate sinus tachycardia before collapse on tilt testing mimicking some features of POTS. These patients may also respond to ivabradine therapy. University Hospital Syncope Clinic where ivabradine was prescribed in a prospective fashion on humanitarian grounds between October 2008 and December 2011.

Twenty-five patients of mean age 33 ± years presenting syncope in all and palpitation in 23, duration 9 ± years underwent tilt testing with reproduction of usual symptoms including tachycardia preceding collapse. Ivabradine was prescribed in doses of 5–20 mg/day, mean 10.7 mg, as once or twice daily medication. The response to treatment was classified as deterioration in none, no change in 5, improvement in 10, and symptoms abolished in 8 patients. Side effects were minimal; one patient required discontinuation.

In this pilot study of ivabradine, in patients with VVS, of patients who demonstrated sinus tachycardia before collapse on tilt, 72% reported a marked benefit or complete resolution of symptoms. The drug was well tolerated. A randomized controlled trial against placebo is justified.

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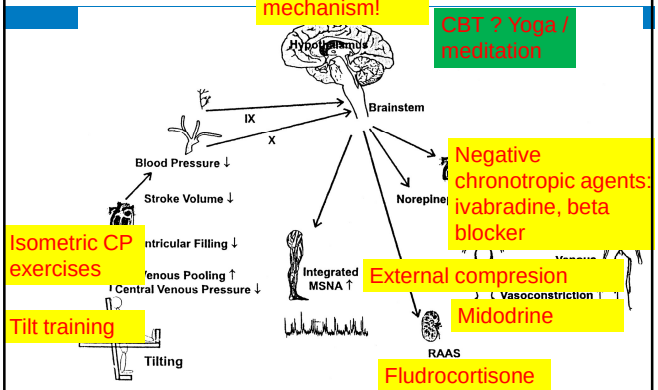
Treatment of syncope based on mechanism

Understanding mechanism!

CBT ? Yoga / meditation



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Yoga / Meditation

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Role of yoga as an adjunctive therapy in patients with neurocardiogenic syncope: a pilot study

Sampath Gunda[1] · Arun Kanmanthareddy[2] · Donita Atkins[1] · Sudharani Bommana[1] · Rhea Pimentel[1] · Jeanne Drisko[3] · Luigi Dibiase[4] · Salwa Beheiry[5] · Steven Hao[5] · Andrea Natale[6] · Dhanunjaya Lakkireddy[1]

Background Neurocardiogenic syncope (NCS) is a common clinical condition characterized by abrupt cardiovascular autonomic changes resulting in syncope. This is a recurring condition with mixed results from current strategies of treatment. *Methods* Subjects with a diagnosis of NCS were screened and enrolled. All the participants were given a DVD containing yoga videos and were instructed to practice yoga therapy for 60 min, three times a week for 3 consecutive months. Syncope functional status questionnaire score (SFSQS) was administered at the beginning and the end of the study. The subjects were followed for 3 months and underwent repeat tilt table testing at the end of the study.
Results Of the 60 patients screened, 44 subjects were enrolled, 21 in the intervention group and 23 in the control group. Most of the participants were females, and the mean age was 21±3 years. In the intervention group, who finished the yoga regimen, there was a statistically significant improvement from control phase to the intervention phase, in number of episodes of syncope (4±1 vs 1.3±0.7, $p<0.001$) and presyncope (4.7±1.5 vs 1.5±0.5, $p<0.001$). The m SFSQS also decreased from 67±7.8 to 29.8±4.6 ($p<0.0$ All subjects had positive head up tilt table (HUTT) study a time of enrollment compared to only six patients at the c pletion of intervention phase (10/100 vs 6/28 %, $p<0.00$ *Conclusion* Yoga therapy can potentially improve the sy toms of presyncope and syncope in young female pat with NCS.

JICE 2015

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2.3 Yoga regimen

The subjects were given a DVD containing self-directed yoga session videos that could be practiced by them according to their convenience at their home or gym. They were instructed to practice yoga therapy for 60 min a day three times a week for 3 months. The yoga sessions consisted of a series of Asanas, Pranayama, and Dhyana. The Asanas refers to isotonic exercises in various bodypostures, Pranayama refers to a series of breathing exercises, and Dhyana refers to meditation. All the subjects were instructed to maintain a log of their yoga activities to ensure adherence.

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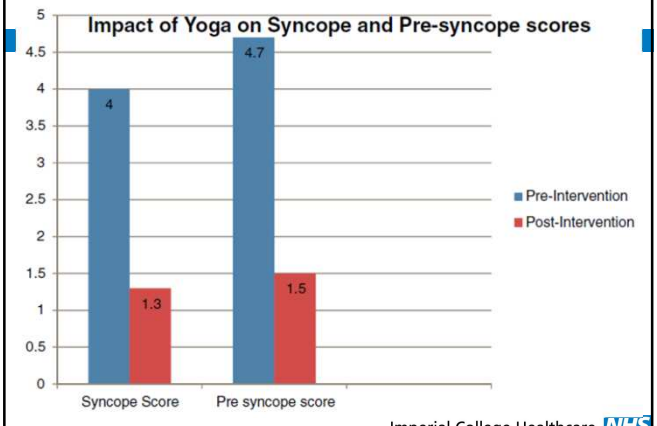

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Effect of Yoga on Arrhythmia Burden, Anxiety, Depression, and Quality of Life in Paroxysmal Atrial Fibrillation

The YOGA My Heart Study

Dhanunjaya Lakkireddy, MD,* Donita Atkins, RN,* Jayasree Pillarisetti, MD,* Kay Ryschon, Sudharani Bommana, MPHIL,* Jeanne Drisko, MD,‡ Subbareddy Vanga, MBBS, MS,§ Buddhadeb Dawn, MD*

Journal of the American College of Cardiology Vol. 61, No. 11, 2013

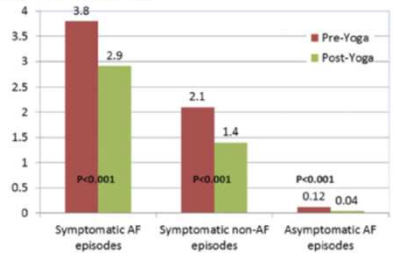

Table 2 Comparison of Baseline, and Pre- and Post-Yoga Intervention Secondary Efficacy Outcome Measures

Type of Score (n = 49)	Baseline (Day 0)	Pre-Yoga (Day 90)	Post-Yoga (Day 180)	p Value
SDS (Depression)	31.0 (27.0–37.0)	29.0 (24.0–35.0)	27.0 (22.0–31.0)	<0.001*
SAS (Anxiety)	34.0 (31.5–37.0)	33.0 (31.0–36.5)	25.0 (23.0–30.0)	<0.001*
SF-36 (domain-wise)				
1. Physical functioning	85.0 (80.0–95.0)	85.0 (70.0–93.8)	90.0 (85.0–95.0)	0.017*
2. Role physical	100.0 (75.0–100.0)	100.0 (56.3–100.0)	100.0 (86.3–100.0)	0.304
3. Bodily pain	100.0 (67.0–100.0)	100.0 (100.0–100.0)	100.0 (100.0–100.0)	0.494
4. General health	65.0 (50.0–77.5)	60.0 (45.0–75.0)	75.0 (65.0–82.5)	<0.001*
5. Vitality	84.0 (68.0–88.0)	84.0 (73.0–91.0)	91.0 (80.0–95.8)	<0.001*
6. Social functioning	100.0 (75.0–100.0)	100.0 (75.0–100.0)	100.0 (90.0–100.0)	0.019*
7. Role emotional	68.0 (60.5–80.0)	68.0 (58.5–80.0)	78.0 (60.5–80.0)	0.212
8. Mental health	75.0 (65.0–85.0)	75.0 (65.0–80.0)	80.0 (70.0–86.0)	<0.001*
Hemodynamic parameters				
Heart rate	66.9 ± 8.3	64.7 ± 7.5†	61.5 ± 7.6†	<0.001
Systolic BP	135.0 ± 7.5	133.0 ± 6.2†	127.7 ± 6.7†	<0.001
Diastolic BP	80.9 ± 7.7	78.2 ± 6.5†	74.0 ± 6.7†	<0.001

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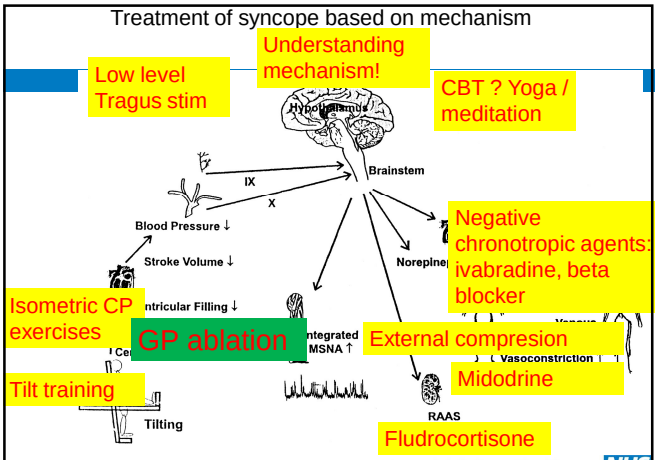
Treatment of syncope based on mechanism



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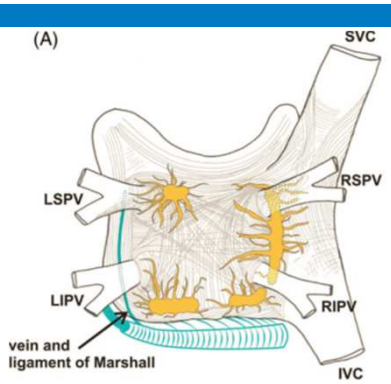
Radiofrequency ablation of ganglionated plexi



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Europace (2011) 13, 1231–1242
doi:10.1093/europace/eur163

CLINICAL RESEARCH
Syncope and Implantable Loop Recorders

Catheter ablation of severe neurally meditated reflex (neurocardiogenic or vasovagal) syncope: cardioneuroablation long-term results

Jose Carlos Pachon M[1,2,3]*, Enrique Indalecio Pachon M[1], Maria Zelia Cunha Pachon[1], Tasso Julio Lobo[1], Juan Carlos Pachon M[1,2], and Tomas Guilhermo Santillana P[1]

[1]São Paulo Heart Hospital—HCor, São Paulo, Brazil; [2]Dante Pazzanese Cardiology Institute, São Paulo, Brazil; and [3]University of São Paulo—USP, São Paulo, Brazil

A total of 43 patients (18F/25M, 32.9 ± 15 years) without apparent cardiopathy (left ventricular ejection fraction=68.6 ± 5%) were included. All had recurrent NMS (4.7 ± 2 syncope/patient) with important cardioinhibition (pauses=13.5 ± 13 s) at head-up tilt test (HUT), normal electrocardiogram (ECG), and normal atropine test (AT). The patients underwent atrial endocardial RF ablation using spectral mapping to track the neurocardiac interface (AF Nest Mapping). The follow-up (FU) consisted of clinical evaluation, ECG (1 month/every 6 months/or symptoms), Holter (every 6 months/or symptoms), HUT (≥4 months/or symptoms), and AT (end of ablation and ≥6 months). A total of 44 ablations (48 ± 9 points/patient) were performed. Merely three cases of spontaneous syncope occurred in 45.1 ± 22 months (two vasodepressor, one undefined). Only four partial cardioinhibitory responses occurred in post-ablation HUT without pauses or asystole (sinus bradycardia). Long-term AT (21.7 ± 11 months post) was negative in 33 (76.7%, $P < 0.01$), partially positive in 7(16.3%), and normal in three patients only (6.9%) reflecting long-term vagal denervation (AT-Δ%HR pre 79.4% × 23.2% post). The post-ablation stress test and Holter showed no abnormalities. No major complications occurred.

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Catheter Ablation as a Treatment for Vasovagal Syncope: Long-Term Outcome of Endocardial Autonomic Modification of the Left Atrium

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Background—Autonomic modification through catheter ablation of ganglionated plexi (GPs) in the left atrium has been reported previously as a treatment for vasovagal syncope. This study aimed to observe the long-term outcome in a larger cohort.

Methods and Results—A total of 57 consecutive patients (aged 43.2±13.4 years; 35 women) with refractory vasovagal syncope were enrolled, and high-frequency stimulation and anatomically guided GP ablation were performed in 10 and 47 cases, respectively. A total of 127 GP sites with positive vagal response were successfully elicited and ablated, including 52 left superior, 19 left lateral, 18 left inferior, 27 right anterior, and 11 right inferior GPs. During follow-up of 36.4±22.2 months (range 12–102 months), 52 patients (91.2%) remained free from syncope. Prodromes recurred in 16 patients. No statistical differences were found between the high-frequency stimulation and anatomically guided ablation groups in either freedom from syncope (100% versus 89.4%, P=0.348) or recurrent prodromes (50% versus 76.6%, P=0.167). The deceleration capacity, heart rate, and heart rate variability measurements demonstrated a reduced vagal tone lasting for at least 12 months after the procedure, with improved tolerance of repeated head-up tilt testing. No complications were observed except for transient sinus tachycardia that occurred in 1 patient.

Conclusions—Left atrial GP ablation showed excellent long-term clinical outcomes and might be considered as a therapeutic option for patients with symptomatic vasovagal syncope. (*J Am Heart Assoc.* 2016;5:e003471 doi: 10.1161/JAHA.116.003471)

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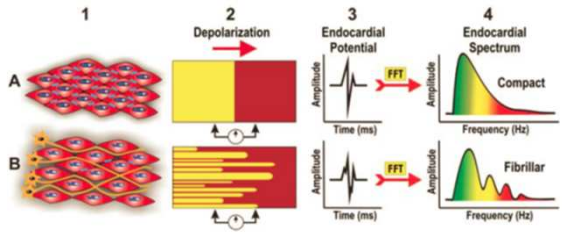

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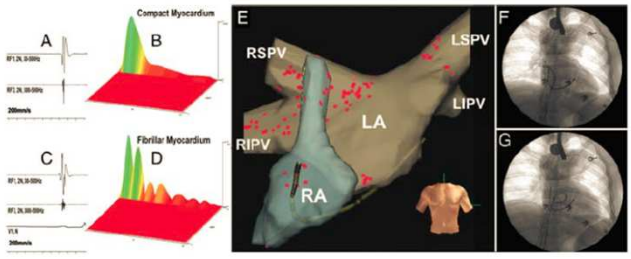

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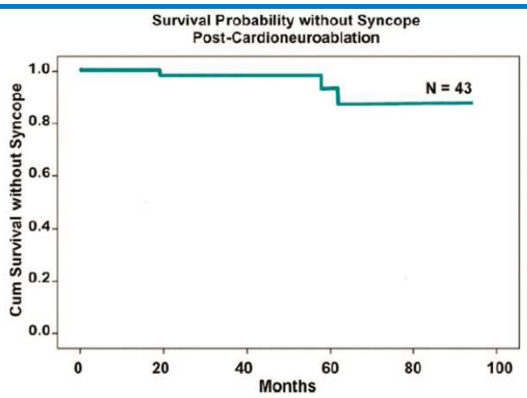
What is problem with this graph?



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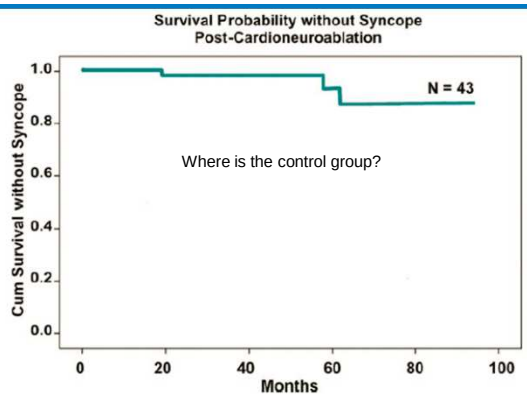

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27yo woman studying postgraduate nursing degree at Southampton

PC: Palpitations and syncope on standing

HPC: Since severe flu in April 2012, missing placements/ lectures due to extreme symptoms of tiredness, lethargy, syncope.

In 2008, similar (less severe) episode of syncope, tilt test confirmed vasovagal syncope, and responded very well to midodrine (alpha-agonist) with complete abolition of symptoms

Case presentation

PMHx: Fit and healthy as child

GI: Since teenage years, suffered with mild irritable bowel (tendency to constipation with abdo pain)

Hypermobile joints

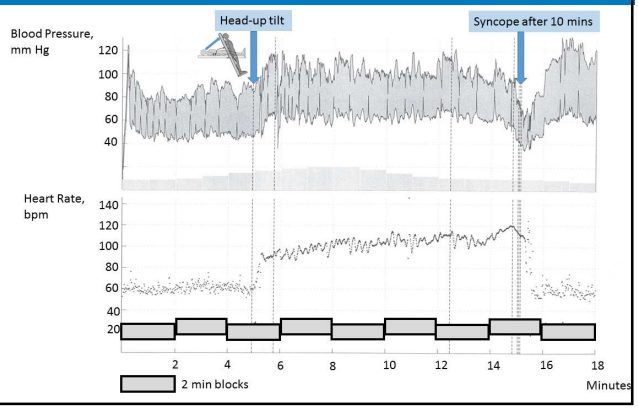
Fluid intake: 2.5L/day, no caffeinated drinks

Dx: Midodrine 10mg tds, fludrocostisone 200mcg od, ivabradine 5mg bd

Patient diary

Date	Time	Systolic	Diastolic	Pulse Rate	Fainting
02-Jul-12	17:15	115	82	73	
03-Jul-12	08:00	108	67	80	
03-Jul-12	12:15	108	68	65	
03-Jul-12	17:00	121	74	72	
03-Jul-12	19:30		FAINT		on way to get more water
04-Jul-12	07:30	106	68	88	
04-Jul-12	12:00	110	73	74	
04-Jul-12	17:00	114	73	78	
05-Jul-12	07:30	109	71	74	
05-Jul-12	12:00	118	76	80	
05-Jul-12	17:00	120	75	71	
06-Jul-12	09:30	107	77	94	
06-Jul-12	11:30		FAINT		walking out of the toilet
06-Jul-12	13:00	123	77	73	
06-Jul-12	17:00	115	71	65	
07-Jul-12	07:30	108	69	68	
07-Jul-12	08:45		NEAR-FAINT		short blackout, dropped glass
07-Jul-12	12:20	109	71	66	
07-Jul-12	17:00	108	66	67	
08-Jul-12	07:30	107	78	111	
08-Jul-12	08:30		FAINT		standing up after shower
08-Jul-12	12:00	114	72	67	
08-Jul-12	18:00	121	75	71	
09-Jul-12	09:30	108	67	79	
09-Jul-12	13:30	113	69	78	
09-Jul-12	17:15	104	76	79	
10-Jul-12	08:30	107	69	78	
10-Jul-12	13:00	116	79	72	
10-Jul-12	17:00	117	70	69	
11-Jul-12	08:30	108	71	84	
11-Jul-12	12:00	119	70	77	
11-Jul-12	16:00		FAINT		standing up from sofa

27yo woman with syncope



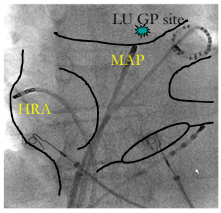
Progress: after 1 year

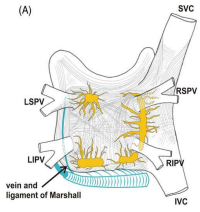
Frequent episodes of syncope for 12 months
Usually with very little warning

Significant injury on a number of occasions:
- Including a subdural haematoma May 2013
- Had to stop physiotherapy sessions for JHS – due to joint pains

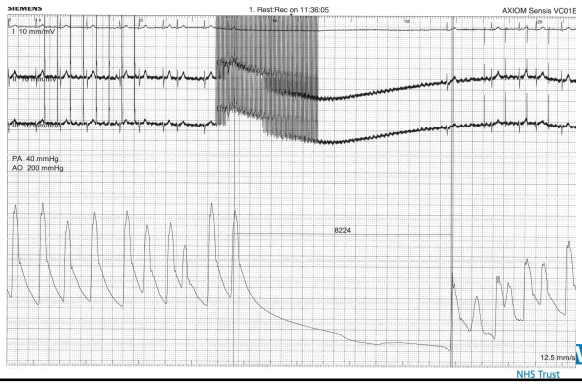
Treatment options?

Cardioneuroablation





AV nodal block with asystole 8s with high frequency stimulation: 20Hz, 10ms, 12V at catheter tip



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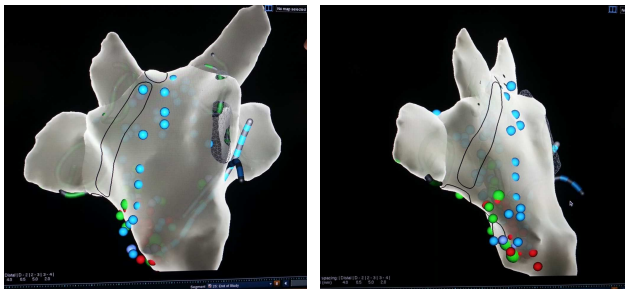
Left atrial 3D Anatomy



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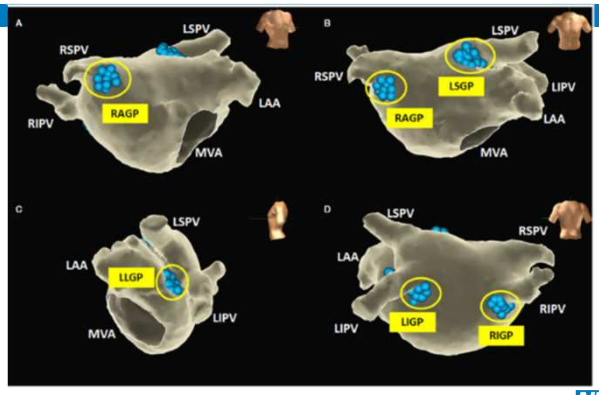
Ablation clusters



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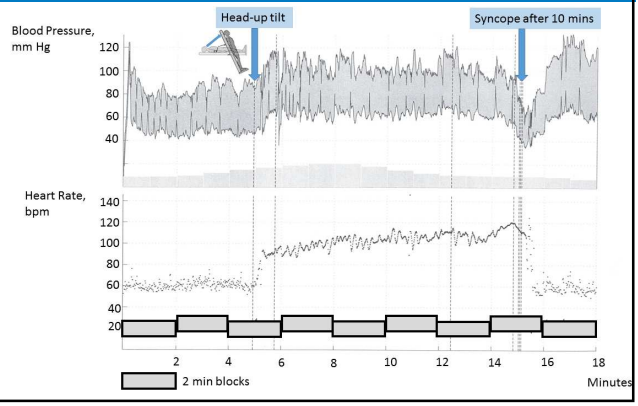
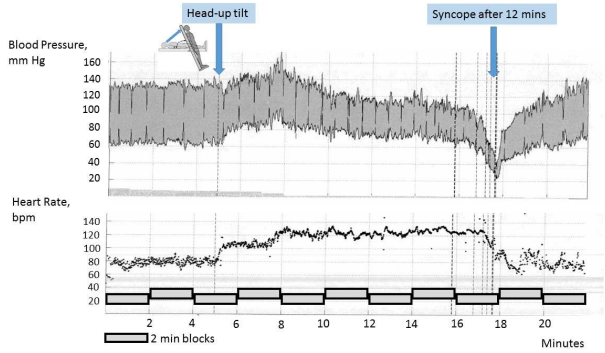
27yo woman with syncope — Tilt table 2008



Tilt table May 2013 – pre-ablation



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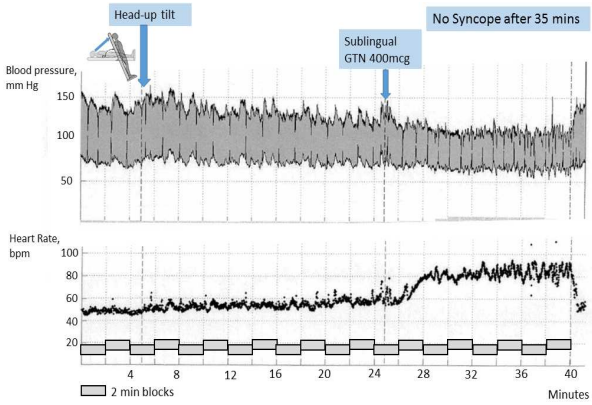
Tilt table Oct 2013 – post ablation



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Progress 36 months on…

Only 6 episodes of syncope , always with warning, and with clear triggers, period pains x 2, joint pains x3, 1 trip in aeroplane whilst dehydrated after holiday

Remains upbeat, back to full time work, and now married

Raising funds for British Heart Foundation Charity!

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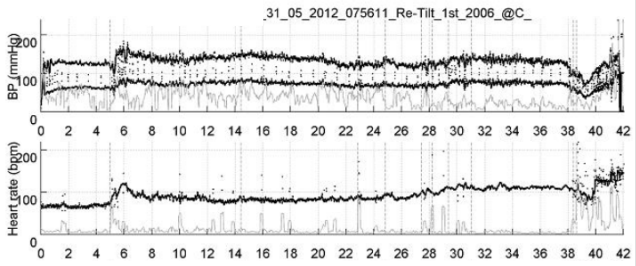
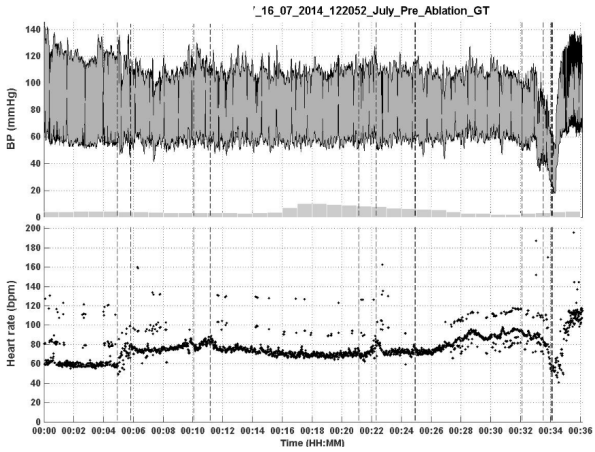
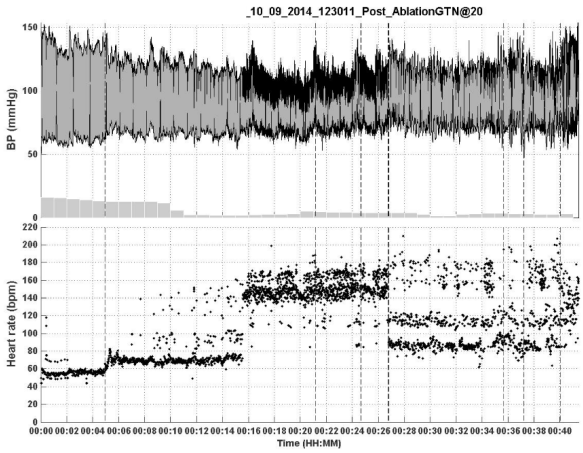
Case 2: 40yo severe drug-refractory symptoms impairing work

- IG, seen in 2006 at 30 with significant worsening symptoms by RS
- Midodrine, fludrocortisone, salt – partially helpful
- Journalist – unable to work , write or sometimes speak, with spells of 6-7 episodes a week.
- Psychology to cope with recurrent events, unhelpful.

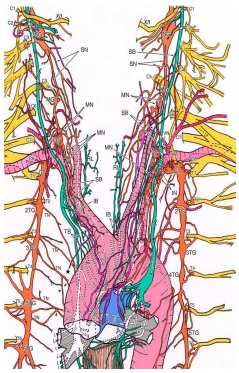
- Ablation Aug 14

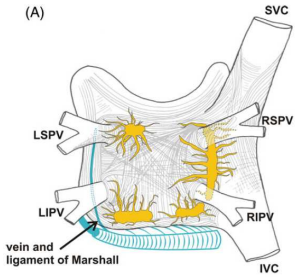






Question: Very profound immediate effect: which reflex/mechanism was targeted with ablation?





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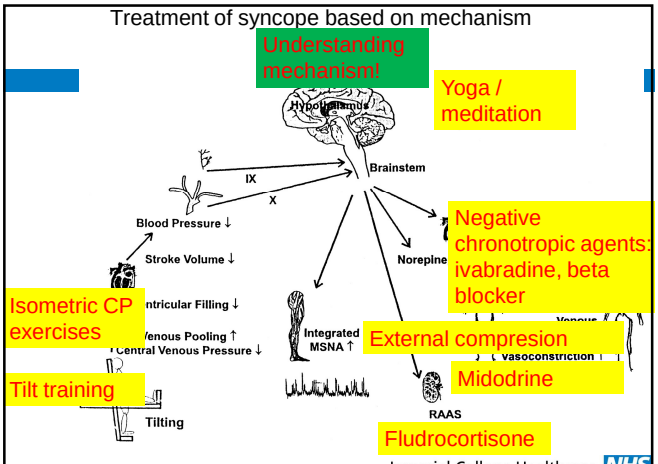
Treatment of syncope based on mechanism

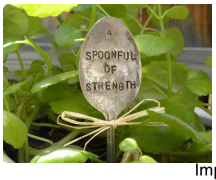


"Novel" Therapy for syncope (personal experience)

- Education
- Education
- Education
- With copious empathy, understanding, good communication, and enough time…

"Novel" Therapy for syncope (personal experience)

- Understanding of pathophysiology
  - "Blood pools in legs, heart is empty"
  - Important to keep vessels "full"
- Syncope is not fully "cured" – but patients can cope well with it
- Acknowledgement of severity of illness
- Understand will have "on" and "off" days
- Reassurance



Summary : Novel therapy for syncope

1. "simple" faint → but pathophysiological mechanisms anything BUT…
2. Gives rise to exciting possibility of robust trials, and cross-collaboration, as well as exploration of novel treatment strategies
3. Any trial needs to consider the 30-40% placebo rate!

Novel treatments for syncope

Boon Lim
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