Cognitive changes following Coronary artery bypass graft

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Neurological difficulties following Coronary artery bypass graft (CABG), such as cognitive decline and depression are well known. The prevalence for cognitive decline has been shown to vary from 33% to 83% and for depression 25%. The aim was to look at cognitive function, depression and anxiety following CABG. The participants were 13 patients that had CABG at Landspitali. They were 10 men and 3 women and they were between the age of 53 and 73 (M = 65.77). Seven cognitive domains were examined with eight different neuropsychological tests, depression and anxiety were examined with Beck's Anxiety Inventory and Beck's Depression Inventory. Patients with cognitive impairment according to EEG measurements were compared to patients with normal cognitive function according to EEG. The groups were compared using independent-samples t-test on the difference that was computed for each participant between pre- and post-surgery. None of the test for the seven cognitive domains and the depression and anxiety appeared to be significant. These results showed that no changes are evident in cognitive function, depression or anxiety measurers following CABG. Since the number of participants was limited the study lacks power and the results should be considered with notice.

Taugafræðilegir erfiðleika eftir opnar kransæðaaðgerðir líkt og vitræn skerðing og þunglyndi eru vel þekktir. Tíðni vitrænnar skerðingar hefur verið sýnd að sé frá 33% til 83% og fyrir þunglyndi er það 25%. Markmið rannsóknarinnar var að athuga vitræna getu, þunglyndi og kvíða í kjölfar opinnar kransæðaaðgerðar. Þátttakendur voru 13 sjúklingar sem höfðu farið í opna kransæðaaðgerð á Landspítalanum. Það voru 10 karla og 3 konur á aldrinum 53 til 73 ára (M = 65,77). Sjö vitræn svið voru skoðuð með átta taugaprófum og þunglyndi og kvíði athuguð með Beck's kvíðakvarða og Beck's þunglyndiskvarða. Sjúklingar með vitræna skerðingu samkvæmt EEG voru bornir saman við sjúklinga með enga vitræna skerðingu samkvæmt EEG. Hóparnir voru bornir saman með óháðu t-prófi á mismuninn á milli fyrir-aðgerð og eftir-aðgerð. Ekkert af prófunum fyrir vitrænu sviðin sjö voru marktæk. Niðurstöðurnar sýna enga breytingu á vitrænni getu, kvíða og þunglyndi í kjölfar opinna kransæðaaðgerða. Taka þarf þó niðurstöðum rannsóknarinnar með fyrirvara þar sem fjöldi þátttakanda var mjög takmarkaður.

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Coronary artery bypass graft (CABG) is performed on about one million people yearly in the world. CABG is used to improve blood flow to the heart and is performed on people with coronary heart disease. Coronary heart disease is when plaque builds up in the coronary arteries. Plaque is mostly made up of fat, cholesterol, calcium and other substances, and can be dangerous because it blocks the coronary arteries causing less blood flow to the heart. This can lead to angina, shortness of breath and heart attack (U.S. Department of Health & Human Services, 2010)

Neurological difficulties following CABG, such as stroke and postoperative delirium, are well known and a great deal of research has been done on that topic (Taggart and Westaby, 2001). The prevalence for stroke following CABG is 3% (Newman et al., 1996; Roach et al., 1996), but high as 9% for patients older than 75 years (Mills, 1995; Tuman, McCarthy, Najafi, & Ivankovich, 1992). In recent years, other factors such as post-operative cognitive deficit, especially depression and long-term cognitive deficit following CABG, have received more interest by researchers (Funder, Steinmetz, and Rasmussen, 2009).

Studies examining CABG have shown various results or prevalence of cognitive decline to be 33% to 83% (Abildstrom et al., 2000; Mahanna et al., 1996; Newman et al., 2001; Shaw et al., 1987; van Dijk et al., 2000). This inconsistency can be traced back to many different causes like different definitions of cognitive decline, inconsistency in neuropsychological tests, different samples and lack of control groups (Blumenthal et al., 1995; Mahanna et al., 1996; Rubens, Boodhwani, and Nathan, 2007; van Dijk et al., 2000). Numerous studies have been published the past 60 years that show evidence of short-term cognitive decline following general surgery (Funder, et. al., 2009; Reichenberg, Dahlman, Mosovich, & Silverstein, 2007). Memory deficit, worse concentration and troubles with problem solving are the main symptoms of short-term cognitive decline (Immer et al., 2003; Lee et al., 2003; Selnes, Goldsborough, Borowicz, & McKhann, 1999). Meta-analysis by van

Dijk et. al. (2000) showed that 22.5% of patients undergoing CABG showed cognitive decline at two months follow-up, which is consistent to results of other meta-analysis (Mahanna et al., 1996).

Even though the majority of researches have focused on short-term cognitive decline recent longitudinal researches have found evidence of long-term cognitive decline for some patients (Reichenberg, et. al., 2007). The symptoms for long-term cognitive decline seem to be more subtle than for short-term decline, and characterized by difficulties such as following instructions, doing math and playing chess (Selnes et al., 2008). For long-term cognitive decline, there has also been some inconsistency in results. Some studies show evidence of long-term cognitive decline (Newman et al., 2001; Selnes et al., 2001; Stygall et al., 2003) while others do not (Hlatky et al., 1997; Mullges, Babin-Ebell, Reents, & Toyka, 2002).

Studies have shown that the majority of people undergoing open-heart surgery experience some depression following the surgery and depression has been shown to have high correlation with coronary diseases (Glassman, 2007; Karlsson, Lidell, & Johansson, 2008). Prevalence of depression following CABG has been shown to be as high as 25% but most studies have not considered mental state before surgery (Frasure-Smith, Lesperance, and Talajic, 1993; Langeluddecke, Fulcher, Baird, Hughes, and Tennant, 1989; Selnes, et. al., 1999). A study by McKhann, Borowicz, Goldsborough, Enger, & Selnes, (1997) showed that patients who were depressed before undergoing CABG showed depression at three and 12 months follow up. Patients who did not have depression before the CABG were not likely to have developed depression at these follow-ups (McKhann, et al., 1997). Studies show that diagnoses of depression following surgery are rare unless depression was present before surgery. Therefore, mental state before surgery is the best predictor of mental state post surgery (Blumenthal et al., 2003; Burg, Benedetto, Rosenberg, & Soufer, 2003; McKhann, et.

al., 1997; Stroobant, van Nooten, De Bacquer, Van Belleghem, & Vingerhoets, 2008; Stroobant & Vingerhoets, 2008; Timberlake et al., 1997).

Electroencephalograms (EEG) are information about electrical activity along the scalp, clinical use of EEG started around the mid-20th century on diagnosis of epilepsy (Cooper, Osselton, & Shaw, 1980; Swartz & Goldensohn, 1998). EEG has been used to examine brain deficit for years and many articles have been published on EEG examination on Alzheimer's disease and various mental illnesses e.g. depression (Jeong, 2004; Thibodeau, Jorgensen, & Kim, 2006).

Not many studies have been made on EEG measurements before and after CABG and the studies that have been made are quite out-dated. Since they were published much progress has been made in the EEG science. A study, in which cognitive function following surgery was evaluated with EEG and neuropsychological tests, showed decline in brain function and cognitive function at 1 week follow-up and 2 months follow-up (Toner, Taylor, Newman and Smith, 1998).

Despite the number of articles published on cognitive function following CABG their results is inconsistent. Many of them are limited methodically which can affect their reliability and validity and reduces their generalisation ability (Rubens, Boodhwani, & Nathan, 2007). It is clear that EEG is very sensitive to small changes in brain function, and their sensitivity and usability in clinical work has increased over the years. A study that combines EEG and cognitive function would monitor short-term and long-term brain and cognitive decline following CABG and make it clearer.

The present study is a pilot study of a larger one being performed. The participants were to have had their CABG and first follow-up at the time the study was conducted. Since the main study is not finished, the number of participants in this study was limited. Patients

with cognitive impairment according to EEG measurements will be compared to patients with normal cognitive function according to EEG. The aims of this study will be:

1. To see if EEG can predict cognitive changes following CABG.
2. To see if EEG can predict changes in anxiety and depression following CABG
3. To see which neuropsychological tests best differentiate normal and cognitive impairment group.

Methods

Participants

The participants were 13 people undergoing open-heart surgery at Landspitali's heart surgery department. They were between the age of 53 and 73 (M = 65.77), 10 males and 3 females. All patients awaiting surgery in that age group were invited to take part in the study. In this study I will look at results of neuropsychological tests for people that have had their heart surgery from the time the study began and until March 2012. Each participant was asked to fill out a consent form (See appendix A) where they were informed about the goals of the research and possible consequences. They were told that they could withdraw from the study at any time and if they would withdraw that it wouldn't affect the service they receive at the hospital. The participants also received an information sheet about the research and what it included (See appendix B). They did not receive any compensation for participating in the study.

Measurement

There are seven cognitive domains that will be tested, verbal memory, non-verbal memory, working memory, motor speed, executive function, visual spatial perception and verbal fluency. Some of the tests measure more than one domain.

The Mini-Mental State Examination (MMSE) is a 30-point test used to screen for cognitive impairment. Scores equal to or greater than 25 indicate no impairment, mild impairment are scores between 21 and 24, moderate impairment are scores between 10 and 20 points and severe impairment are scores equal to or lower than 9 points (Tómasson, 1986).

Verbal memory was examined with The Rey Auditory-Verbal Learning Test (RAVLT) (Strauss, Sherman and Spreen, 2006). RAVLT consists of wordlists with 15 words that are read to the participant and he is to try to remember the words. He gets five attempts and then after 30 minutes he is asked to recollect those words.

Non-verbal memory, immediate and delayed, was tested with Rey Osterrieth Simple Figure (Becker, o.fl., 1987). In this test the participant is asked to copy a picture by hand immediately after seeing the picture and then 30 minutes later.

Working memory was estimated with the digit span forward test. Participant is asked to repeat a number sequence after the researcher in forward order (Kaplan, et. al., 1991).

Psychomotor speed was evaluated with the Grooved Pegboard test, the digit symbol test (DSST) and Trails A test. In the Grooved Pegboard test the participant is asked to place 25 key shaped pins into appropriate holes as fast as he can first with his right hand and then with his left hand (Ruff and Parker, 1993). The DSST evaluates concentration and attention. In this test the participant is asked to put a correct symbol below a number ranging from 1-9 as fast as he can in no more than two minutes (Wechsler, 1981). In Trails A test, the participant is asked to connect numbers in the correct sequence as quickly as possible (e.g 1-2-3-4) (Tombaugh, 2004).

Executive function was tested with Trails B test, Digit span backwards test, Stroop test and verbal fluency H words and S words test. In Trails B test the participant is supposed to connect numbers and letters together in right sequence (e.g. 1-A-2-B) as quickly as possible (Tombaugh, 2004). In Digit span backwards test the participant is supposed to repeat after the researcher series of numbers in backwards order (Kaplan, Fein, Morris and Delis, 1991). In the Stroop test the participant is being tested in inhibiting automatic reflexes when he is asked to name the colours of words instead of reading the word. The word is e.g. “red” but the colour of the word is blue (Stroop, 1935). In the Verb fluency H test the participant is asked to name as many word as he can that start with the letter H in one minute, the S test is the same but with words that start with the letter S (Strauss, et. al., 2006).

Visual spatial function and organization was tested with the Rey Osterrieth Simple Figure, the copy part of that test is used to test visual spatial perception, but that is when the participant is asked to copy the picture by hand while looking at it (Becker, et. al., 1987).

Verbal fluency was tested with the Verbal fluency animal test and Digit span forward test. In the Verbal fluency animal test the participant is asked to name as many animals as he can in one minute (Strauss, Sherman and Spreen, 2006).

Anxiety and depression was measured with Beck's anxiety inventory (BAI) and Beck's depression inventory (BDI) (Beck, o.fl., 1988; Beck, 1988).

EEG (electroencephalogram) was recorded using NicoletOne EEG Systems from CareFusion®. Subsequent analysis was done in the Matlab environment from The MathWorks®. The recording was conducted by placing 25 electrodes on the scalp and record brain activity for 10 minutes. For the first five minutes of the recording, the patient was asked to lie still with his eyes closed and try not to move his eyes and stay quiet. During the remaining five minutes the patient was asked to keep his eyes closed and then open them for 30 seconds and repeat that five times. While the EEG was being recorded a cardiogram was also being recorded to monitor the effects of the heartbeat on the EEG.

Design

The design was 2 x 2 mixed design – group (normal cognition x cognitive impairment) – time (pre surgery x post surgery). Participants were assigned to group according to their EEG measures. The EEG was analysed according to a classification method Mentis Cura has developed. In that analysis each individual's EEG were compared to a database of 1050 EEG's that the company has gathered since the year 2000. Using statistical pattern recognition each participants EEG was classified into one of the following groups: Normal and cognitive impairment (CI).

There were two independent variables, the EEG measurement, that is whether the participant showed cognitive impairment or not and the CABG surgery. The dependent variable was the cognitive function as measured by the tests described above.

Procedure

Those agreeing to participate in the study met with the researcher, Magnús Jóhannsson, on two occasions for about two hours each time. The baseline assessment was conducted in the weeks before the surgery and then once following surgery, about two to five months after the surgery. At both meetings, all the measurements described above where administered. After signing the informed consent each participant was asked to fill out the BAI and the BDI as well as questions related to background information. Then, following necessary preparation and placement of the electrodes, EEG was recorded. Finally, the neuropsychological assessment was conducted.

Statistical analysis

For statistical analysis of the neuropsychological tests SPSS was used. The difference between pre- and post-surgery for each participant was computed. Then the normal group and the cognitive impairment group were compared using independent-samples t-test on the difference that was computed between pre- and post-surgery.

Results

The normal group and the cognitive impairment group (CI) were compared using independent-samples t-test on the difference between pre- and post-surgery. The difference between pre- and post-surgery was obtained by computing the difference between pre- and post-surgery for each participant. No statistical difference was apparent between the groups on any of the neuropsychological tests on these points in time.

Verbal memory

In Table 1 the descriptive statistics for RAVLT, RAVLT delayed and recognition are presented. There was no significant difference between the groups on these tests because both of the groups are showing improvement between pre- and post-surgery.

Table 1 - Descriptive statistics for Verbal memory

		Pre-Surgery			Post-surgery		
	EEG measures	Mean	Std. Deviation	N	Mean	Std. Deviation	N
RAVLT	Normal	40.167	8.542	6	44.667	8.189	6
	Cognitive impairment	38.143	10.319	7	40.857	9.754	7
	Total	39.077	9.206	13	42.615	8.912	13
RAVLT - Delayed	Normal	6.670	2.805	6	8.330	2.066	6
	Cognitive impairment	5.710	3.147	7	6.860	2.545	7
	Total	6.150	2.911	13	7.540	2.367	13
RAVLT - Recognition	Normal	13.670	1.366	6	14.000	1.095	6
	Cognitive impairment	12.710	3.684	7	13.140	1.676	7
	Total	13.150	2.794	13	13.540	1.450	13

*p = .01

Non-verbal memory

Table 2 shows the mean points for the Rey Osterrieth simple figure immediate and delayed. No difference was apparent according to the t-test since the CI group showed no

change while the normal group showed a small decline in the immediate condition. In the delayed condition the groups showed no difference that was significant.

Working memory

The means for Digit span forward test are presented in Table 2. Both the normal group and the CI group showed a decrease in mean score between pre-surgery and post-surgery, the difference was however very small and non significant.

Table 2 - Descriptive statistics for Non-verbal and working memory

		Pre-Surgery			Post-surgery		
	EEG measures	Mean	Std. Deviation	N	Mean	Std. Deviation	N
Rey Osterrieth Simple Figure Immediate	Normal	18.167	2.714	6	17.583	3.137	6
	Cognitive impairment	17.143	5.178	7	17.143	5.329	7
	Total	17.615	4.094	13	17.346	4.284	13
Rey Osterrieth Simple Figure delayed	Normal	17.917	2.654	6	17.750	4.287	6
	Cognitive impairment	16.417	5.499	6	17.714	4.162	7
	Total	17.167	4.191	12	17.731	4.040	13
Digit Span Forward Test - Points	Normal	8.170	2.401	6	7.830	1.941	6
	Cognitive impairment	8.860	2.478	7	8.570	2.149	7
	Total	8.540	2.367	13	8.230	2.006	13

*p = .01

Psychomotor speed

Table 3 shows descriptive statistics for Grooved pegboard test, DSST and Trails A. In the Grooved pegboard test right hand both of the groups show little as none difference between pre- and post-surgery. In Grooved pegboard test left hand the normal group shows improvement in time while the CI group showed decline in time, that difference did however appear to be non-significant.

In the DSST test both of the groups show a very little change in mean score between pre- and post-surgery. In the Trails A test the normal group improves from pre-surgery to post-surgery while the CI group shows a small decline. However as stated in the beginning of this chapter the difference was not significant.

Table 3 - Descriptive statistics for Psychomotor speed

		Pre-Surgery			Post-surgery		
	EEG measures	Mean	Std. Deviation	N	Mean	Std. Deviation	N
Grooved Pegboard Test - right hand	Normal	83.20	19.842	5	84.75	8.342	4
	Cognitive impairment	94.00	13.379	5	94.57	24.711	7
	Total	88.60	16.939	10	91.00	20.293	11
Grooved Pegboard Test - left hand	Normal	99.60	25.344	5	72.50	44.426	4
	Cognitive impairment	108.80	22.863	5	113.67	21.21	6
	Total	104.20	23.266	10	97.20	36.875	10
DSST	Normal	43.33	8.981	6	44.83	9.152	6
	Cognitive impairment	39.57	18.573	7	38.29	18.759	7
	Total	41.31	14.488	13	41.31	14.913	13
Trails A	Normal	57.00	26.736	6	39.50	16.682	6
	Cognitive impairment	64.14	29.650	7	65.43	30.604	7
	Total	60.85	27.407	13	53.46	27.663	13

DSST = Digit symbol test
*p = .01

Executive function

Table 4 shows descriptive statistics for Trails B, Digit span backwards test, stroop test and verbal fluency test. In trails B test both of the groups show an increase in mean time between pre-surgery and post-surgery, the difference between the groups is however not large enough to be significant. In the Digit span backwards test both groups show an increase in score between measuring points not large enough though.

In Stroop test – time, both the normal and the CI group show a decline in mean time between measurements, though the decrease is stronger for the normal group and very little for the CI group.

For the Stroop test – color, both groups show a decrease in mean time between pre-surgery and post-surgery, though the CI group shows a little more decrease than the normal group the difference is however non significant. In Stroop test – disturbance, the normal group shows a noticeable decrease in mean time between pre-surgery and post-surgery while the CI group shows an increase in their mean time. This difference approached significance since $t(11) = 2.905$, $p = .014$.

In Verbal fluency test H-words, the normal group shows a decrease in mean score between pre-surgery and post-surgery while the CI group shows an increase in score. For Verbal fluency S-words the same thing is apparent it is however non significant for both of the groups.

Visual spatial function and organization

Table 5 shows descriptive statistics for Rey Osterrieth simple figure – copy part. For that test both of the groups show no difference between pre- and post-surgery.

Verbal fluency

In Table 6 the descriptive statistics for Verbal fluency test – animal words are presented. The table shows that the normal group showed a very small improvement while the CI group showed a small decline in mean score between pre- and post-surgery.

Anxiety and depression

Table 7 shows means and standard deviation for Beck's Anxiety Inventory (BAI) and Beck's Depression Inventory (BDI). On the BAI test both groups showed a decrease in anxiety between pre-surgery and post-surgery but the CI group showed less anxiety at both time points than the normal group. Both groups also showed a decrease in depression between

measurements but in contrary to the anxiety test the normal group showed less depression than the CI group. None of this difference was however significant.

Table 4 - Descriptive statistics for Executive function

		Pre-Surgery			Post-surgery		
	EEG measures	Mean	Std. Deviation	N	Mean	Std. Deviation	N
Trails B	Normal	102.00	17.799	6	107.00	27.814	6
	Cognitive impairment	172.29	100.204	7	198.43	118.223	7
	Total	139.85	80.514	13	156.23	97.781	13
Digit Span Backward Test	Normal	5.330	.816	6	6.000	2.098	6
	Cognitive impairment	4.290	1.604	7	4.860	2.116	7
	Total	4.770	1.363	13	5.380	2.103	13
Stroop Test Time	Normal	26.330	3.204	6	24.670	2.875	6
	Cognitive impairment	29.710	10.626	7	29.570	11.028	7
	Total	28.150	7.988	13	27.310	8.410	13
Stroop Test - Colors	Normal	35.170	3.817	6	34.170	3.189	6
	Cognitive impairment	37.140	8.194	7	32.860	15.604	7
	Total	36.230	6.379	13	33.460	11.244	13
Stroop Test - Disturbance	Normal	78.170	14.552	6	68.170	12.766	6
	Cognitive impairment	69.140	11.866	7	75.000	19.647	7
	Total	73.310	13.437	13	71.850	16.537	13
Verbal Fluency Test - H-words	Normal	12.500	6.950	6	10.000	5.621	6
	Cognitive impairment	10.570	4.685	7	11.290	3.861	7
	Total	11.460	5.666	13	10.690	4.590	13
Verbal Fluency Test - S-words	Normal	15.500	7.314	6	14.170	8.495	6
	Cognitive impairment	10.000	3.367	7	10.710	4.821	7
	Total	12.540	6.009	13	12.310	6.701	13

*p = .01

Table 5 - Descriptive statistics for Visual spatial function and organization

		Pre-Surgery			Post-surgery		
	EEG measures	Mean	Std. Deviation	N	Mean	Std. Deviation	N
Rey Osterrieth Simple Figure copy - Points	Normal	22.167	2.137	6	22.000	1.095	6
	Cognitive impairment	21.429	2.820	7	20.929	1.742	7
	Total	21.769	2.454	13	21.423	1.525	13
Rey Osterrieth Simple Figure copy - Time	Normal	141.200	54.108	5	101.000	22.477	6
	Cognitive impairment	128.714	45.405	7	126.000	55.573	7
	Total	133.917	47.228	12	114.462	43.851	13

*p = .01

Table 6 - Descriptive statistics for Verbal fluency

		Pre-Surgery			Post-surgery		
	EEG measures	Mean	Std. Deviation	N	Mean	Std. Deviation	N
Verbal Fluency Test Animal-words	Normal	18.670	6.623	6	19.830	4.355	6
	Cognitive impairment	17.710	6.873	7	16.710	6.370	7
	Total	18.150	6.492	13	18.150	5.550	13

*p = .01

Table 7 - Descriptive statistics for anxiety and depression questionnaires

		Pre-Surgery			Post-surgery		
	EEG measures	Mean	Std. Deviation	N	Mean	Std. Deviation	N
BAI	Normal	9.17	7.055	6	6.33	9.522	6
	Cognitive impairment	7	9.747	7	3.43	4.315	7
	Total	8	8.337	13	4.77	7.026	13
BDI	Normal	6.5	3.271	6	3.5	4.93	6
	Cognitive impairment	7.86	6.492	7	5.29	5.345	7
	Total	7.23	5.102	13	4.46	5.027	13

*p = .01

Discussion

Since this study is only a pilot study and the number of participants is limited the power is not very great. Originally, the participants were supposed to be more, but because of technical reasons that changed. Even though this study lacks power and it is not possible to generalise these results it is possible to see if they set a trend for the main study. It is hard to address one of the aims, that is whether EEG does predict cognitive changes following CABG since these results were very vague due to lack of power.

None of the tests showed statistical difference, the Stroop test disturbance did however approach statistical difference that could indicate some trend in the results. That test showed that while the normal group got better after the surgery the CI group got worse. This result is in line with what was expected, that is that the CI group would get worse than the normal group. It is however interesting that the normal group gets much better after surgery, that could be due to training effects but than it would probably also be apparent for the CI group. Stroop test tests concentration and problem-solving but earlier researches have revealed evidence that suggest that short-term decline in concentration and problem-solving is evident following CABG (Immer et al., 2003; Lee et al., 2003; Selnes, Goldsborough, Borowicz, & McKhann, 1999).

It is also noticeable for other tests in executive function that the normal group is in general doing better than the CI test to the difference between pre surgery and post surgery is not significant. It is also interesting that CI group has a much higher standard deviation on some tests in executive function which points to more variability there and could that be due to different degree of cognitive impairment.

The results show that the EEG can most likely not predict changes in anxiety and depression following CABG. But looking at the means for the groups it shows that both groups decrease in both anxiety and depression. The normal group is however higher in

anxiety than CI group at both measurements, that effect is however reversed for depression where CI group is higher than normal group. It is interesting that when looking at the data for each participant then it can be seen that most of them who showed anxiety before surgery showed improvement post surgery. This effect can be due to anxiety because of the coronary heart disease and even the surgery but symptoms of anxiety attacks are e.g. fear of dying or getting a heart attack. For these individuals that fear is real since they have a coronary artery disease and are about to undergo a big surgery.

The last aim of this study was to see which neuropsychological tests best differentiate the groups. Stroop test disturbance did so and there was evidence for it in the other tests in executive function, that effect was also apparent in psychomotor speed even though none of it was significant. In psychomotor speed the normal group is performing much better on all of the tests. That might suggest that the cognitive impairment that the EEG detects has much effect on psychomotor speed, but that effect is not apparent on all of the cognitive domains. In verbal memory the normal group has shows a better performance than the CI group but both of the groups are showing improvement after the surgery. For working memory the effect is reversed, that is both of the groups deteriorate after surgery. The effects of the surgery vary across domains in this study, it will be interesting to see how the results for the main study will be, if more participants will give results in some other direction or the same. It could be interesting to see if EEG predicts cognitive decline in some cognitive domains more than others with regard to the results of psychomotor speed. There the cognitive impairment detected with EEG seems to affect psychomotor speed while it doesn't affect some of the other domains as much.

There are a few shortcomings in this research. For instance there was a lack of participants that affected the results. It will, however, be interesting to see if this study can predict some results for the main study when it is finished. I would also have been better to

look at long-term effects of the surgery since some studies have presented evidence of that (Newman et al., 2001; Selnes et al., 2001; Stygall et al., 2003) it will however be examined in the main study.

One thing to consider when using the same neuropsychological tests at two points is the training effect. Icelandic neuropsychological tests are limited in that way there is only one version of each available. For tests like RAVLT and Rey Osterrieth simple figure it is possible that training effects occur, since there are only three to five months between measurements.

Research like this one is important since CABG is one of the most common surgery performed, and there are still many dangers that can follow it. This surgery is also being performed on increasingly older individuals and they tend to have more comorbid diseases like hypertension and diabetes.

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Appendices

Appendix A – Consent form

UPPLÝST SAMÞYKKI

Með undirskrift minni hér að neðan staðfesti ég að hafa fengið bæði munnlegar og skriflegar upplýsingar um rannsóknina „**Opnar kransæðaaðgerðir, vitræn geta, þunglyndi og heilarit** “

Ég staðfesti að hafa lesið og skilið upplýsingar um tilgang, markmið, tímalengd og fyrirsjáanlegar afleiðingar af rannsókninni og til hvers verður ætlast af mér. Einnig hef ég verið upplýst(ur) um hugsanlega áhættu og ávinning rannsóknarinnar. Mér var gefinn tími og tækifæri til að spyrjast fyrir um rannsóknina og öllum mínum spurningum var svarað fullnægjandi.

Ég hef fengið upplýsingar um að þátttaka mín sé frjáls og að ég geti hvenær sem er dregið til baka loforð mitt um þátttöku án þess að rökstyðja það nánar.

Ég staðfesti að ég hef upplýst starfsmann rannsóknarinnar um öll hugsanleg lyf sem ég hef tekið á undan eða sem ég hef áætlað að taka, hvort sem þau eru lyfseðilsskyld eða ekki.

Ég hef verið upplýst(ur) um tryggingar þátttakenda.

Ég hef verið upplýst(ur) um að ef ég dreg samþykki mitt til baka mun það ekki hafa áhrif á þá þjónustu sem ég kann að þurfa með í framtíðinni á heilbrigðisstofnunum.

Ég samþykki skráningu klínískra upplýsinga sem tengjast rannsókninni, ópersónugreinanlega úrvinnslu þeirra og geymslu.

Ég samþykki að starfsmenn rannsóknarinnar hafi aðgang að gögnum um mig í gagnagrunni skuðrdeildar LSH sem koma að gagni í rannsókninni, með því skilyrði að upplýsingarnar séu meðhöndlaðar sem trúnaðarmál og að aðgangur hafi verið samþykktur af Persónuvernd.

Ég samþykki að starfsmenn rannsóknarinnar hafi aðgang að sjúkraskrám mínum á sjúkrahúsum, öldrunarstofnunum og sérfræðingum til að sækja upplýsingar sem koma að gagni í rannsókninni, með því skilyrði að upplýsingarnar séu meðhöndlaðar sem trúnaðarmál og að aðgangur hafi verið samþykktur af Persónuvernd.

Mér hefur verið tilkynnt að rannsóknin sé gerð samkvæmt ákvæðum Helsinki-sáttmálans og leiðbeiningum um góða klíníska starfshætti í lyfjarannsóknum (ICH-Good Clinical Practice).

Mér hefur verið skýrt frá því að ópersónugreinanlegar upplýsingar og niðurstöður verða varðveittar varanlega eða þar til starfsemi Mentis Cura ehf. verður lögð niður. Persónugreinanleg gögn verða varðveitt þar til rannsókn er lokið.

Ég samþykki að taka þátt í rannsókninni.

Ég mun fá afrit af þessu undirritaða samþykki.

Dagsetning (sem þátttakandi ritar)	Undirskrift þátttakanda
	Nafn þátttakanda í prentstöfum
| | | | | | – | | | |	Kennitala þátttakanda

Ég staðfesti að ég hef útskýrt tilgang, markmið og fyrirsjáanlegar afleiðingar rannsóknarinnar fyrir þátttakandanum, en nafn hennar/hans er skráð að ofanverðu.
Þátttakandinn samþykkir þátttöku sína með undirskrift sinni hér að ofan.

Dagsetning	Undirskrift rannsóknarstarfsmanns

Appendix B – Information sheet

Upplýsingar til þátttakenda í rannsókninni:

Opnar kransæðaaðgerðir, vitræn geta, þunglyndi og heilarit

Þér er boðið að taka þátt í rannsókn þar sem verið er að kanna áhrif opinna kransæðaaðgerða á vitræna getu og þunglyndi. Á meðfylgjandi blaðsíðum er lýsing á rannsókninni.

Ábyrgðamaður rannsóknarinnar er Jón Snædal, yfirlæknir á Landakoti, Sími: 543 9800, Tölvufang: jsnaedal@landspitali.is. Meðrannsakendur eru Tómas Guðbjartsson prófessor á hjartaskurðdeild og samstarfsmenn þeirra.

Þessi rannsókn er gerð í samstarfi við rannsóknar- og þróunarfyrirtækið Mentis Cura ehf., Grandagarði 7, 101 Reykjavík.

Rannsóknin hefur fengið umfjöllun í Vísindasiðanefnd og fengið leyfi hennar og einnig hefur verið fengið leyfi Persónuverndar.

Rannsóknin er framkvæmd í samræmi við góða klíníska starfshætti í rannsóknum (ICH-Good Clinical Practice) og fylgir í öllu ákvæðum Helsinki sáttmálans.

Gott er að ætla sér nægan tíma til að lesa þessar upplýsingar. Þér er velkomið að spyrja spurninga ef eitthvað er óljóst eða ef frekari upplýsinga er þörf.

Ef þú samþykkir að taka þátt í rannsókninni ert þú beðin(n) um að undirrita samþykkisyfirlýsingu við upphaf rannsóknarinnar. Þú færð síðan afrit af undirrituðu yfirlýsingunni.

UPPBYGGING RANNSÓKNARINNAR

Tilgangurinn með rannsókninni er að kanna áhrif opinna hjartaaðgerða á vitræna getu svo sem minni og þunglyndi en vitað er að sumir sem fara í slíkar aðgerðir fá slík einkenni í kjölfarið. Áhrifin verða metin með taugasálfræðilegum prófum og með heilaritum.

Rannsóknin er byggð þannig upp að hver þátttakandi hittir rannsakendur þrisvar, liðlega tvo klukkutíma í senn. Einu sinni fyrir aðgerð og tvisvar eftir aðgerð eða 2-3 mánuðum og einu ári eftir aðgerð. Í hvert skipti fer fram taugasálfræðilegt mat ásamt því að heilarit er mælt og þátttakandi beðinn um að svara sjálfsmatskvörðum sem meta þunglyndi og kvíða.

Reiknað er með að um 200 manns taki þátt í rannsókninni.

Rannsóknin getur farið fram á mörgum stöðum eftir hentugleika því auðvelt er að flytja mælitækin á milli staða. Í flestum tilfellum fara mælingarnar fram á skurðlækningasviði Landspítala Háskólasjúkrahúss við Hringbraut en einnig hjá Mentis Cura að Grandagarði 7, 101 Reykjavík eða heima hjá einstaklingum sé þess þörf.

Framkvæmd rannsóknarinnar

Þátttakandi skrifar undir samþykkisyfirlýsingu eftir að hafa fengið kynningu á rannsókninni og fengið svör við öllum spurningum sem kunna að vakna.

Heimsóknir eru þrjár alls og skiptist hver þeirra í þrjá hluta:

1. Heilarit

Heilaritsmæling er framkvæmd með því að tengja rafnema við höfuðið og mæla heilarit í 10 mín. Heilaritsmælingin er algjörlega sársauka- og hættulaus.

Á meðan heilaritið er mælt ert þú beðin(n) um að hreyfa sem minnst augu og höfuð. Einnig ert þú beðin(n) um að tala ekki á meðan verið er að mæla heilaritið þar sem öll þessi áreiti hafa áhrif á ritið. Ef þú finnur til óþæginda, þá ert þú hvött(hvattur) til að láta vita.

Það er **nauðsynlegt að þvo hárið eftir mælinguna**, því notað er leiðnigel til að tylla rafnemunum á höfuðið. Gelið skolast auðveldlega af með vatni og sápu.

Einfalt hjartalínurit er mælt á meðan á heilaritsmælingu stendur til að fylgjast með áhrifum hjartsláttar á heilaritið.

Reikna má með að ein klukkustund fari í hverja mælingu heilarits.

2. Taugasálfræðilegt mat

Taugasálfræðilegt mat felur í sér lausn ýmissa verkefna sem líkjast eins konar þrautum eða gátum. Þessi verkefni reyna á flest svið vitrænnar getu eins og minni, einbeitingu, athygli, stýrihæfni og sjónræna úrvinnslu.

Verkefnin taka rúma klukkustund.

3. Sjálfsmatskvarðar lagðir fyrir

Sjálfsmatskvarðar fyrir þunglyndi og kvíða eru stuttir spurningarlistar sem tekur í kringum 10 mínútur að svara.

Reikna má með 2½ klukkustund í heimsóknina.

Þátttakendur eru hvattir til að hafa samband/ræða við rannsakendur ef þeir finna fyrir einhverjum óþægindum.

HVAÐA UPPLÝSINGUM VERÐUR SAFNAÐ?

Upplýsingar sem skráðar eru um þig í gagnagrunni skurðdeildar verða nýttar til að kanna hvort það séu einhver atriði þar sem geta varpað ljósi á það ef vitræn skerðing eða þunglyndi verður í kjölfar opinna kransæðaaðgerða. Búið er að sækja um leyfi frá Persónuvernd um

þessa samkeyrslu gagnanna. Það er nauðsynlegt fyrir okkur að hafa upplýsingar um þau lyf sem þú ert að taka á þeim tíma sem heilaritið er tekið. Vinsamlega hafðu því meðferðis í allar heimsóknirnar upplýsingar um lyfjanotkun þína.

AÐ TAKA ÞÁTT

Þátttaka þín er frjáls. Hafna má þátttöku eða draga samþykki sitt til baka hvenær sem er án skýringa og mun það engin áhrif hafa á þá læknisþjónustu sem þú getur þurft á að halda nú eða í framtíðinni. Ef þú óskar eftir að draga samþykki þitt um þátttöku til baka, skalt þú tafarlaust hafa samband við framkvæmdaraðila eða lækni rannsóknarinnar.

Endi gæti verið bundinn á þátttöku þína í rannsókninni ef læknir rannsóknarinnar metur að það sé þér fyrir bestu.

ÁHÆTTA/ÁVINNINGUR MEÐ ÞÁTTTÖKU Í RANNSÓKNINNI

Með rannsókninni er verið að greina breytingar á heilastarfsemi í kjölfar opinnar kransæðaaðgerðar með tilliti til vitrænnar skerðingar og þunglyndis. Það getur því komið þér til góða að fá útlistun á því hvernig eða hvort heilastarfsemi þín breytist eftir slíka aðgerð og þá hvort breytingin er til skamms tíma eða nær yfir að minnsta kosti eitt ár.

Engin áhætta fylgir taugasálfræðilegu mati eða því að mæla heilarit, en óþægindi geta hlotist af því að hár og höfuð verði klístrað vegna leiðnigels. Notast er við leiðnigel til að tylla rafskautunum á höfuðleðrið. Gelið skolast úr hári með volgu vatni og sápu.

TRYGGINGAR

Þátttakendur eru tryggðir fyrir hvers kyns skaða sem rannsóknin kann að valda.

GREIÐSLA FYRIR ÞÁTTTÖKU

Ekki verður greitt sérstaklega fyrir þátttöku í rannsókninni.

MEÐFERÐ PERSÓNUUPPLÝSINGA

Farið verður með allar upplýsingar sem trúnaðarmál. Þetta á einnig við um taugasálfræðilegu prófin, sjálfsmatskvarðana og heilaritin og úrvinnslu á þeim. Ef niðurstöður mælinganna verða birtar á opinberum vettvangi, svo sem í ritrýndum fagtímaritum, þá verða gögnin ekki persónugreinanleg.

Öll úrvinnsla gagna verður ópersónugreinanleg.

Að rannsókn lokinni verða gögnin gerð ópersónugreinanleg. Öll heilaritagögn, sem safnað verður, eru varanleg eign Mentis Cura ehf. Öll rannsóknargögn verða varðveitt varanlega hjá Mentis Cura ehf. Leggist starfsemi fyrirtækisins niður þá verður öllum gögnum eytt sem eru geymd hjá Mentis Cura ehf.

FREKARI UPPLÝSINGAR

Óskir þú eftir frekari upplýsingum um rannsókn þessa, má hafa samband við:

Gísla H. Jóhannesson	*Framkvæmdastj. klínískra rannsókna*	*Mentis Cura ehf.*
Sími: 530 9900 Bréfsími: 530 9901	Gsm: 824 7747	

Ásdísi L. Emilsdóttur Sími: 530 9900 Bréfsími: 530 9901	*Rannsóknarfulltrúa* Gsm: 8982526	*Mentis Cura ehf.*
Magnús Jóhannsson Sími: 543 4068	*Sálfræðing* Gsm 8955215	*Landspítala*

Ef þú hefur spurningar um rétt þinn sem þátttakandi í vísindarannsókn eða vilt hætta þátttöku í rannsókninni getur þú snúið þér til Vísindasiða-nefndar, Vegmúla 3, 108 Reykjavík, Sími: 551 7100, fax. 551 1444.

Jón Snædal, yfirlæknir,
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